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13. ABSTRACT *(Maximum 200)*

The Georgetown team developed and installed a teleradiology network linking Bosnia, Hungary and Germany. Without the technical and clinical infrastructures that were developed through this CRADA, such rapid deployment would not have been possible.

We have concluded a successful demonstration project for interactive tele-urology between Georgetown University Medical Center, Washington, DC and Martinsburg City Hospital, West Virginia. We also focused on establishing the minimum technical requirements in telemedicine. A dialysis network has been established for the evaluation studies. Multimedia data base design for telemedicine of dialysis service is underway. A new project using telemedicine for pharmacology telementoring is in progress. We have developed a telepathology network using the Internet. Economic modeling, confidentiality and data security studies of telemedicine have been developed and will be applied initially to the network of kidney dialysis services.

The ISIS team conducted a number of training sessions on the use of computed radiography at DOD sites in the States and Korea. We have also developed a CR Training School, in which a number of DOD personnel have participated. The Georgetown team participated in the design and programming of the Second National Forum: Military Telemedicine On-Line Today.

Research in breast palpation, spine surgical simulation and prostate biopsy optimization are underway to help us further define data base requirements for all types of digital images.

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Geoffrey Lich 10/24/96

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Executive Summary

Akamai Project Annual Report
Year 2 (October 1995 - September 1996)

The Akamai Research Project is a collaborative research program between Georgetown University Medical Center (GUMC) and the USAMRMC to support the DOD's efforts in teleradiology, telemedicine and digital imaging network projects such as the Medical Diagnostic Imaging Support (MDIS) network.

Digital radiology and teleradiology remain the core competencies of the Georgetown group. The results of this CRADA became the foundation for successful rapidly deployable teleradiology systems in Bosnia to support the U.S. troops. The Imaging Science and Information Systems (ISIS) Center team developed and installed a teleradiology network linking Bosnia, Hungary and Germany. Although actual deployment and continuing support is funded by a separate contract, without the technical and clinical infrastructures that were developed through this CRADA, such rapid deployment would not have been possible.

In order to enhance the performance of teleradiology and MDIS, we are conducting research in data compression, and experimenting with home teleradiology systems using off-the-shelf software and standards. We have developed a training program in computed radiography (CR) and an international conference in military telemedicine.

We have had significant progress in various aspects of telemedicine research. We have concluded a successful demonstration project for interactive tele-urology between Georgetown University Medical Center, Washington, DC and Martinsburg City Hospital, West Virginia. We also focused on establishing the minimum technical requirements in dealing with electronic stethoscope and real time ultrasound. A dialysis link has been established for the evaluation studies. Multimedia data base design for telemedicine of dialysis service is underway with the School of Engineering, George Mason University. A new project using telemedicine for pharmacology telementoring is in progress. We have developed a telepathology network using the Internet for which we are currently developing technical protocols. Economic modeling of telemedicine has been developed and will be applied initially to the network of kidney dialysis services. Protocol to study confidentiality and data security in telemedicine applications has been established.

The ISIS team conducted a number of training sessions on the use of CR at DOD sites in the States and Korea. We have also developed a CR Training School, in which a number of DOD personnel have participated. To promote effective use of telemedicine capabilities, the ISIS Team participated in the design and programming of the Second National Forum: Military Telemedicine On-Line Today (General Russ Zajtchuk, MD, President).

While a digital imaging network focuses on the rapid distribution of radiological images for timely diagnosis, it does little in the use of images of advanced applications such as surgical simulation or 3-D visualization. Once the network is in place, it can serve as a powerful infrastructure to facilitate these advanced applications. Research in breast palpation, spine surgical simulation and prostate biopsy optimization will help us to further define data base requirements for all types of digital images.

Akamai Annual Report

Chapter 1

Rapid Deployable Teleradiology

1.1 Teleradiology and the Military: Support of the US Troops in Bosnia

Primary Investigators

Betty A. Levine, MS
Kevin Cleary, PhD

1.0 Introduction

As part of the NATO peace keeping Implementation Force (IFOR), 20,000 US troops were deployed to Bosnia-Herzegovina in December 1995. A decision was made to support deployment of advanced technologies to augment the medical capabilities of the US troops. Advances in medical imaging and diagnostics, satellite communications, and computer internetworking proved critical to the DOD decision to implement telemedicine, including teleradiology, to support the troops in Bosnia. In an effort to provide high quality medical care, rapid and definitive response to trauma, and maximize patient return to duty while minimizing soldier movement, Operation Primetime III was initiated. DEPRAD - Deployable Radiology - is part of Operation Primetime III.

The ISIS Center at Georgetown University Medical Center was selected as the system integrator for this effort to design, develop, and implement a deployable teleradiology system that could support remote diagnosis of radiology images generated in Bosnia and Hungary. Two requirements of the DEPRAD implementation were that commercial off the shelf (COTS) telemedicine equipment be used and that sufficient military and commercial telecommunications support be provided by the DOD to support the telemedicine network. The DEPRAD team worked within these requirements to design an off the shelf teleradiology network that provides connectivity between multi-vendor systems and allows for transmission of digital radiology images anywhere in the world at anytime.

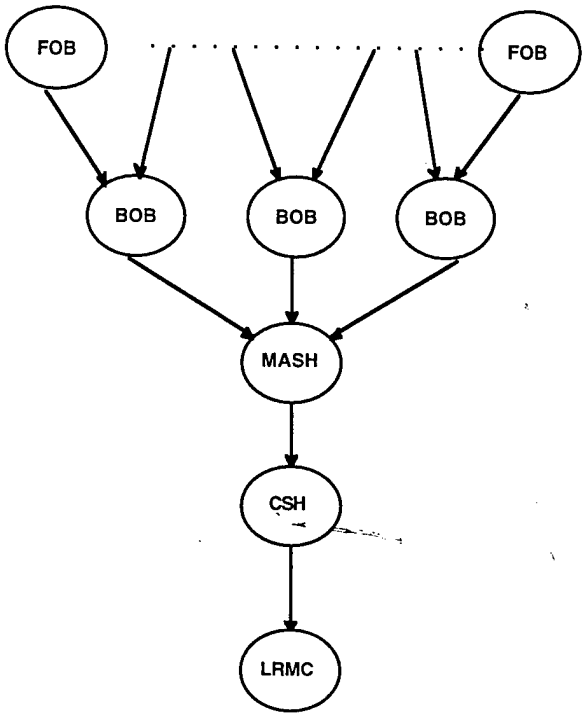
2.0 Military Medical Care

There are 5 echelons of military medical care. These include the forward operating bases (FOBs), the brigade operating bases (BOBs), the mobile army surgical hospital (MASH), the combat support hospital (CSH), and a European full service hospital. The FOBs have no radiological imaging capabilities but do have other medical support. There are multiple FOBs in Bosnia. The BOBs have conventional x-ray imaging and a single x-ray technologist as well as other medical support. There are 3 BOBs in Bosnia. The MASH has radiological imaging support, and x-ray technologists, but has no radiologist. There is only one MASH within Bosnia. The CSH in Hungary has radiological imaging, multiple x-ray technologists, and a radiologist. Finally, the Landstuhl Regional Medical Center (LRMC) is a complete medical center located in Landstuhl Germany and is the final stop in the European echelon of care before a soldier is sent back to the continental US (CONUS). A diagram of the echelons of care is shown in Figure 1.

The FOBs and BOBs are located throughout Bosnia in an effort to provide medical care to the troops throughout the region. Although medical facilities are limited at the FOBs and BOBs, they serve an important role in providing medical care to the deployed troops. Patients are first seen at these sites before the decision is made to transport them to the MASH. Since there is only a single MASH in Bosnia to support all 20,000 deployed troops, it is not conveniently located to all troops. Transport of personnel within Bosnia is difficult due to weather conditions and terrain, and due to the potential risk to the troops. There are over 2 million land mines still in place in Bosnia and troop movement is highly controlled. Convoys, with a minimum of 4 vehicles and 8 healthy soldiers, are required to transport personnel anywhere around Bosnia. Helicopters flying in and

out of Bosnia must fly in groups of 2 or more with guns in the ready position. Therefore, bringing high quality care to the troops is preferable than bringing the troops to the care. Phase II of the DEPRAD deployment will provide teleradiology support to the BOBs through film digitizer and Inmarsat communications. As troops require more advanced medical care, they are evacuated from the 212th MASH first to the 67th CSH in Taszar, Hungary and then to the LRMC in Landstuhl, Germany before being sent stateside.

Figure 1. Echelons of Care



The rules governing assignments of personnel to the different echelons of military medical care do not provide for a radiologist to be assigned to the MASH. Therefore, before the installation of DEPRAD, x-ray images taken at the MASH were read by non-radiologist medical doctors or the patient and their films were evacuated to the CSH before a primary diagnosis could be attained. The positive impact that DEPRAD could have on medical care for the troops in Bosnia became evident and the military saw this as an excellent opportunity to test teleradiology in a deployed environment. The Army has been involved with teleradiology and picture archiving and communications systems (PACS) for many years. However, these capabilities have never been deployed in such an environment before.

3.0 Configurations

The DEPRAD systems integration team worked closely with military personnel to understand the different echelons of military medical care and the imaging modalities available or desired at each level of care. With this information the DEPRAD team designed an off-the-shelf teleradiology network that provided real-time primary diagnosis to the MASH in Bosnia. The imaging modalities provided by the Army included Picker PQS CT scanners equipped with a 3M 8700 Dry View film printer, conventional x-ray imaging, and a Diasonics ultrasound unit with an ALI DICOM interface box in Bosnia. Working with this equipment, the remaining tasks were to:

- select and implement computed radiography (CR)
- select and implement softcopy display stations
- develop a local area network (LAN) to connect imaging devices to display stations
- provide technology to use the 3M 8700 film printer as a network accessible printer
- provide a diagnostic quality solution for getting old films into the imaging network
- provide for the transfer of images between Bosnia, Hungary, and Germany as required
- provide for the transfer of images to other locations via the Internet or a secure military wide area network

The DEPRAD team insisted on the DICOM 3.0 medical imaging communications standard for any equipment connected to the network. The Picker PQS CT scanner and the Diasonics Ultrasound machine with the ALI gateway had DICOM 3.0 interfaces. The 3M 8700 film printer did have a DICOM print server, however we later determined that additional software was required to use this print server on our network. A CR reader, a CR DICOM gateway, display stations, and a film digitizer still needed to be selected.

A Fuji AC-3 computed radiography reader was selected for computed radiography because of its cost, size, image quality, and Georgetown's expertise in working with the device. The Analogic CR DICOM gateway was selected because the image processing algorithms implemented on the gateway were Fuji approved. This gateway receives the Fuji CR images from a proprietary interface, applies Fuji approved image processing algorithms and passes the images through a DICOM interface

A single vendor was selected to supply display stations to facilitate training, maintenance, and service. One of the defining factors for selecting the Siemens MagicView workstations was the availability of 2Kx2K monitors. It was felt that 2Kx2K display was essential since the CR produces 2K image datasets and the American College of Radiology (ACR) recommends the full dataset be used for teleradiology. Displaying the 2K image set on a 1K monitor is not always convenient for the radiologist.

The communications network at each site requires each imaging modality to send directly to the radiology display station. Each imaging modality, often through the use of second-party software and/or hardware, is able to produce a DICOM 3.0 store message to transfer images to the Siemens MagicView. The MagicView is configured to receive DICOM 3.0 messages from each imaging modality and to send DICOM store messages to the 3M Dry View print server to produce hard copy films when needed.

DICOM compliance was a requirement established by the ISIS integration team in selecting equipment for the DEPRAD network. The use of a communications standard like DICOM would facilitate system integration. Many vendors claim to have DICOM compliant systems. These vendors produce the required DICOM conformance statements which theoretically allow one to determine the level of DICOM conformance between multiple vendors. But few vendors DICOM interpretations are plug-and-play connections. Among the seven DICOM implementations we encountered for this project, none were connected without some modification to configuration files, changes or patches required by vendors, or requiring operational changes by the user.

MASH:
At the 212th MASH, the following equipment is in place:

- Picker PQS CT scanner
- Diasonics US machine with an ALI interface box
- Fuji AC-3 CR device with an Analogic SD-100 CR gateway
- Lumisys Lumiscan 75 laser film digitizer (LFD) with a Dejarnette Image Share workstation
- 3 Siemens MagicView display stations

Radiology

MagicView 500

Single normal Luminance 1K monitor

2 GB of disk storage

MOD drive for archival

ICU, EMT

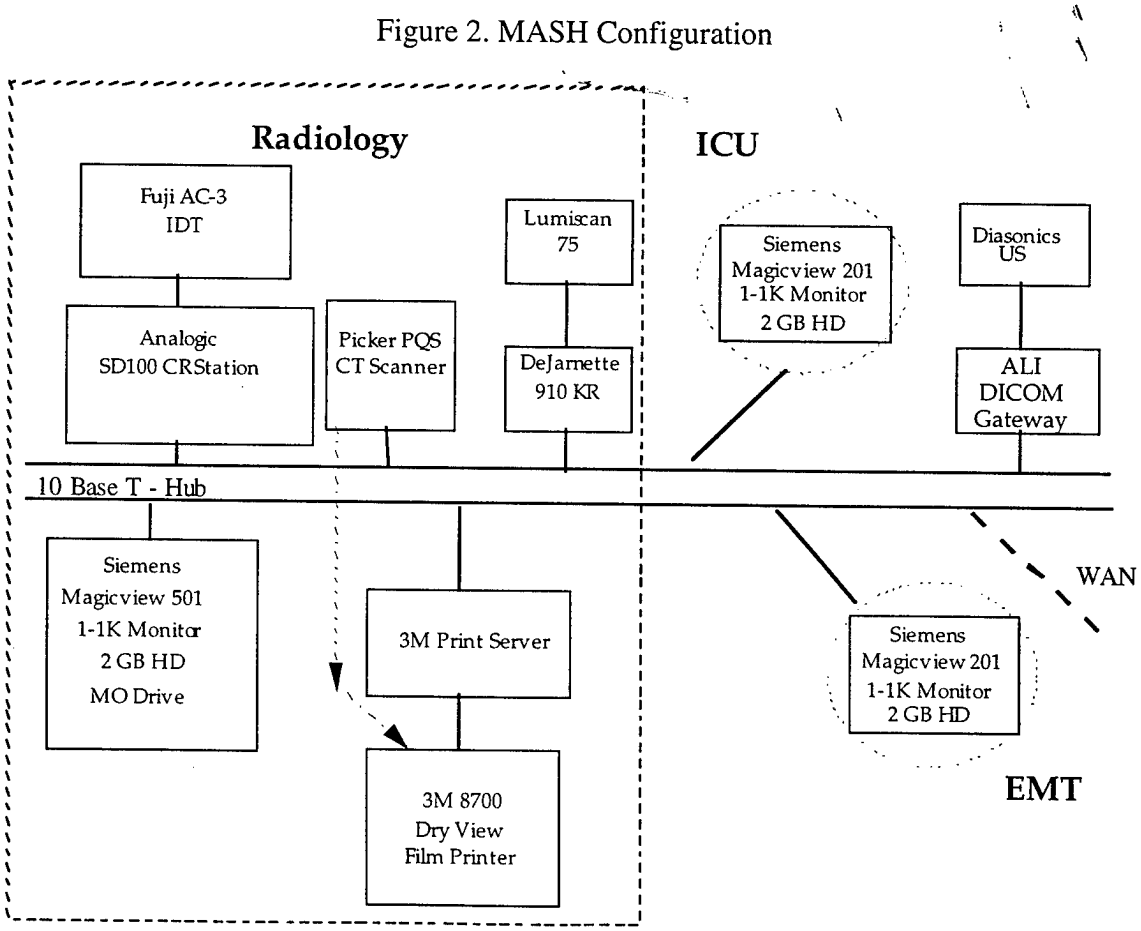
MagicView 200

1 Single normal Luminance 1K monitor

2 GB of disk storage

- 1 3M 8700 Dry View film printer

Figure 2. MASH Configuration



CSH:
At the 67th CSH, the following equipment is in place.

- 1 Picker PQS CT scanner
- 1 Fuji AC-3 CR device with an Analogic SD-100 CR gateway
- 1 Lumisys Lumiscan 75 laser film digitizer (LFD) with a Dejarnette Image Share workstation
- 6 Siemens MagicView display stations

Radiology

MagicView 500

2 high luminance 1K monitor

9 GB of disk storage

1 MOD drive for archival

MagicView 1000

2 Megascan 2K monitors

2 GB of disk storage

ICU, Orthopedics, EMT, Physician Consult area

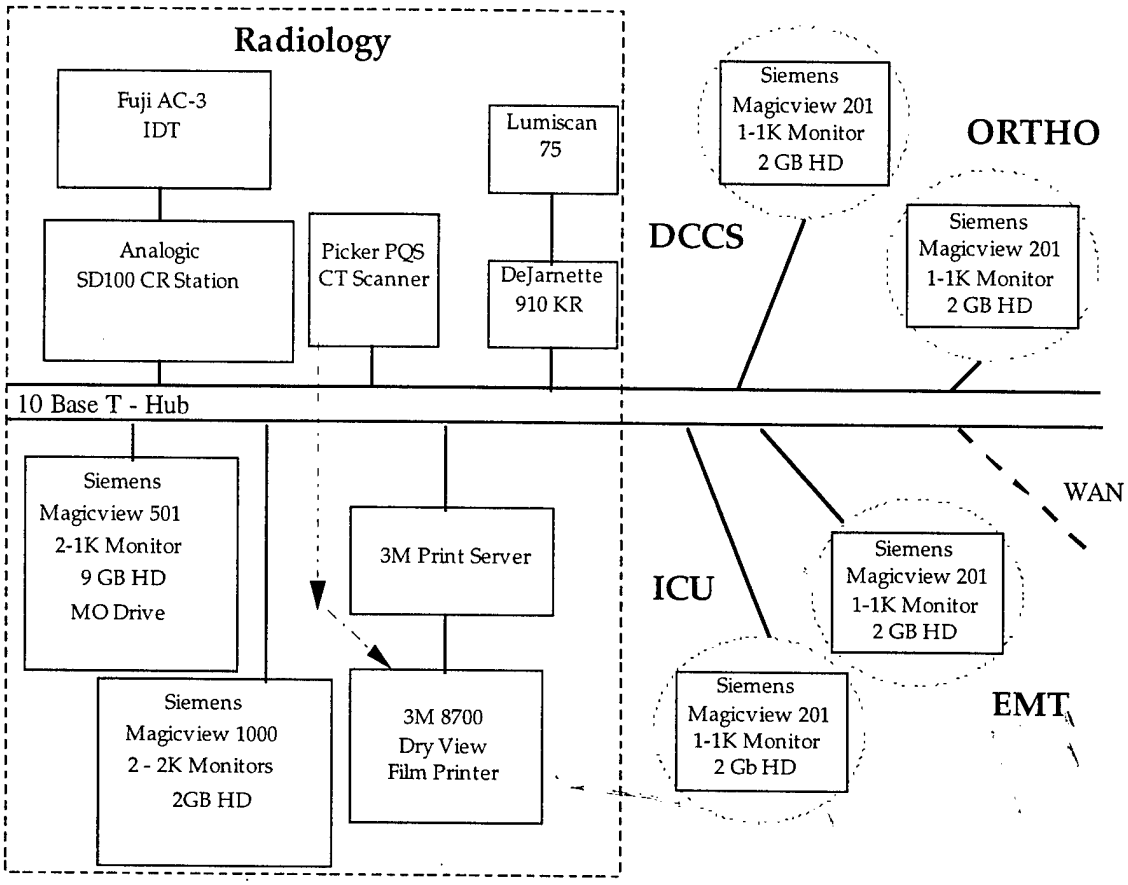
MagicView 200

Single normal Luminance 1K monitor

2 GB of disk storage

- 1 3M 8700 Dry View film printer

Figure 3. CSH Configuration



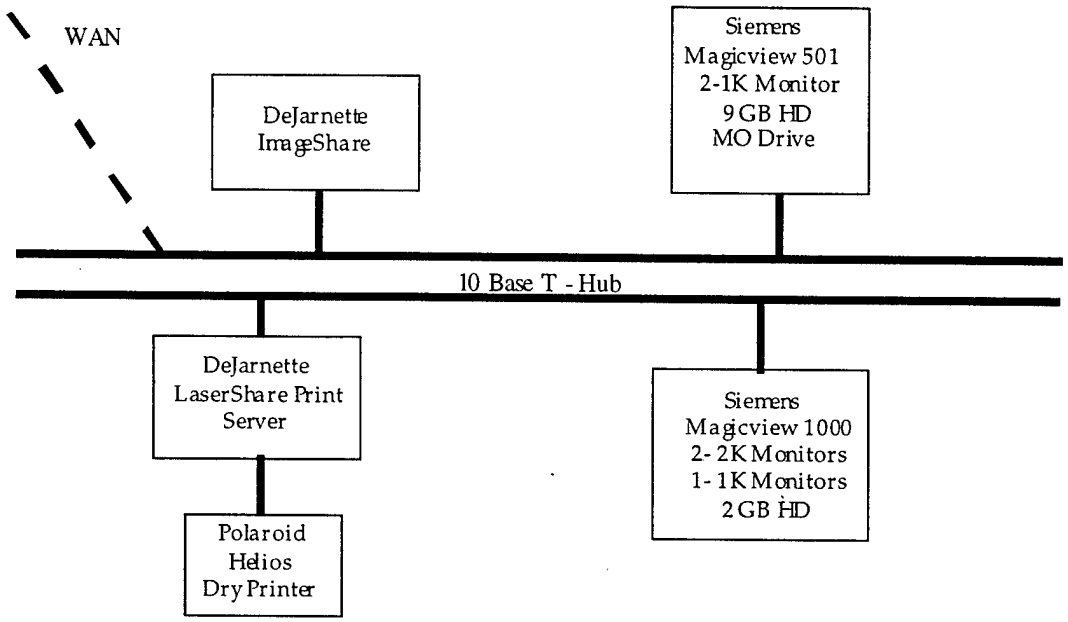
LRMC:
At LRMC, the following equipment is installed.

- 2 Siemens MagicView display stations
  Radiology

MagicView 500
2 high luminance 1K monitor
9 GB of disk storage
1 MOD drive for archival
MagicView 1000
2 Megascan 2K monitors
2 GB of disk storage

- 1 Polaroid Helios dry film printer
- 1 Dejarnette Internet gateway

Figure 4. LRMC Configuration



DepRAD Project, ISIS Center, 7 Jan 96

4.0 Communications

Wide area network communications were established by the US military with the assistance of GTE personnel. The communications infrastructure is a 10BASE-T local area network (LAN) at each site for internal communications of images. There is a microwave antenna and satellite in place for wide area network (WAN) communications between the MASH and the CSH and LRMC. Leased E-1[1] lines from the Hungarian and German telephone companies provide for communications between Germany and Hungary. A diagram of the communications links is shown in figure 5.

Images are transmitted out of Bosnia via microwave from the MASH to Tuzla air base (10 miles away), then through satellite communications to a satellite farm in Landstuhl Germany, and then over leased E-1 lines to the CSH or LRMC. The theoretical maximum transfer rate that is available through this satellite and over the leased lines is approximately 2.048 megabits per seconds. Communications between the CSH and LRMC are leased E-1 lines. Internet access is available at all sites so that images can be transferred to other military institutions like Tripler Army Hospital for backup clinical support. The Georgetown team continues to support and maintain the systems daily via the Internet.

[1] An E-1 line is the European equivalent of a T-1 line and provides a 2.048 megabits/second capacity

Figure 5. Data communications network

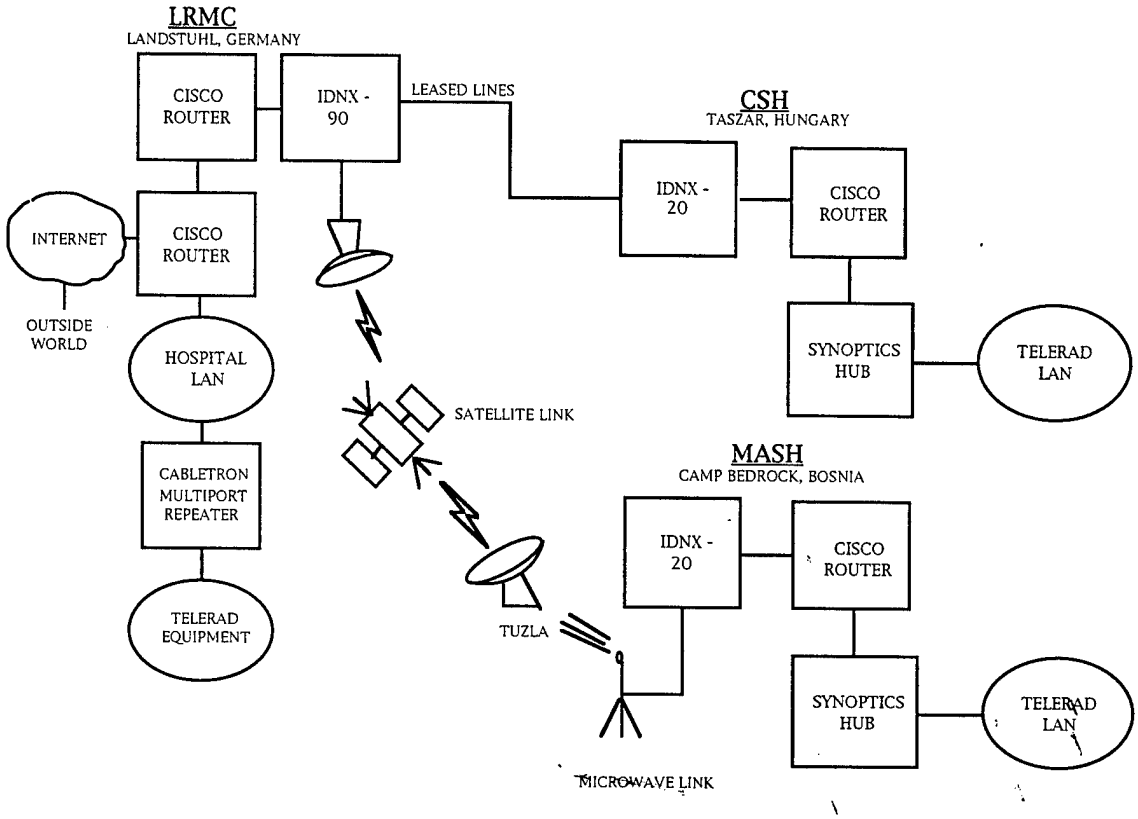


Image transfer on the LAN is sufficient for this application. A 7-10 MB image (a single CR or LFD image) is transferred between the imaging modalities and the workstation in under 2 minutes. Images are transferred between local workstations in under 30 seconds. Image transfer from the MASH to the CSH or LRMC takes approximately 10 minutes and between the CSH and LRMC in about 2 minutes. Over the Internet, transfer times vary considerably dependent on time of day and can take from 20 minutes to more than 60 minutes for a single CR image.

5.0 Clinical Scenarios

Images are acquired digitally at the MASH and CSH. Since there is no radiologist stationed at the MASH all images acquired at the MASH are sent to the CSH for primary diagnosis. Simultaneously, images are transferred within the MASH and CSH to local workstations and/or printed on the 3M 8700 printer as needed. Printing is done for foreign nationals or other UN troops who need to take a copy of their images with them and for surgical cases. All diagnosis is done softcopy at the CSH. It was initially thought that all images would be sent to LRMC (from both the CSH and MASH) for permanent archival. However, it became evident shortly after implementation that it was not practical to transfer all the images to LRMC, so the permanent archive is maintained at the CSH. Images are transferred to LRMC only if the patient is evacuated to LRMC or if a radiologist is unavailable at the CSH.

Once studies are diagnosed at the CSH, the radiologist will log into the Composite Health Care System (CHCS) at the MASH and enter the diagnostic report. The images and the reports are then available at the MASH quickly. Images are sent to the CSH usually in a batch mode at the end of the day. Emergency cases are transferred immediately and reports either phoned back to the MASH or recorded in CHCS immediately to ensure fast turn around times.

6.0 Continued Support & Maintenance

Georgetown University ISIS center continues to support the systems daily. Initially upon return from overseas, the daily support was tremendous. Approximately 10 hours a day were spent on support. However, as the systems stabilized and the sites became more comfortable with the equipment support needs have diminished greatly.

Daily, all the systems are checked to verify continued operations, that disks aren't full, and that no errors have occurred. Usage statistics are captured to monitor how much the systems are being used and what if any changes are required. One significant change that was noted from this daily monitoring was the work load at the MASH was higher than originally expected. Conversely, the number of image transfers to LRMC was less than expected. Thus, in response to actual usage, the primary workstations at the MASH and LRMC were swapped to provide 9 GB of storage to the MASH and 2 GB to LRMC.

Image quality problems have been diagnosed remotely by having images sent to Georgetown over the Internet. An image quality concern was raised at the MASH a few weeks after initial installation. Images were sent from the MASH to Georgetown where a radiology technologist and physicist who are experts on CR imaging viewed them, talked with the Fuji engineers and were able to determine the cause of the problem. A computer board was accidentally left in the CR reader and was causing degradation of the image quality under certain circumstances. Medical maintenance personnel at the MASH removed the board and they were operational again within days.

To ensure that problems can be diagnosed and recreated and new software tested prior to deployment in the field, a prototyping and integration lab has been setup at Georgetown. Much of the same equipment that is installed in Bosnia, Hungary, and Germany has been purchased and installed so that software fixes and new software releases can be tested, and problems recreated to better diagnose them without affecting clinical operations in the field.

7.0 Statistics

The teleradiology network has been used extensively since it was installed. Since mid-May, system usage has been carefully tracked. The statistics provided here are from mid-May until September. Computed radiography is used almost exclusively at the MASH and CSH and a chart of CR usage is shown in Figure 6. Over 2700 CR images have been acquired at the MASH, and over 1600 at the CSH. The computed tomography (CT) equipment has been used for over 150 patient studies, with the majority of these done at the MASH. There have been 67 ultrasound (US) studies performed at the MASH.

Every image acquired at the MASH is sent to the CSH for archival on a magneto-optical disk (MOD). There have been over 550 patient folders sent to the CSH from the MASH. A patient folder normally consists of one type of exam (CR, CT, or US) with a CR folder typically containing 1 to 8 images, a CT folder about 30 images, and an US folder about 20 images. In July, when the radiologist at the CSH was on vacation, about 200 patient folders were sent from the MASH and CSH to LRMC. Also, during a four day visit to the MASH by the CSH radiologist, more than 40 patient folders were sent from the CSH to the MASH for primary diagnosis. As can be seen from these statistics, this is an excellent example of teleradiology since the images can be sent to any location where there is a radiologist.

While printing is available at all the sites, filmless radiology is the primary mode of operation. In the first 8 weeks of statistics gathering, we estimate that approximately 45 patient folders were printed at the MASH and CSH combined with the majority of these printed at the MASH where they see more foreign nationals.

8.0 Conclusion

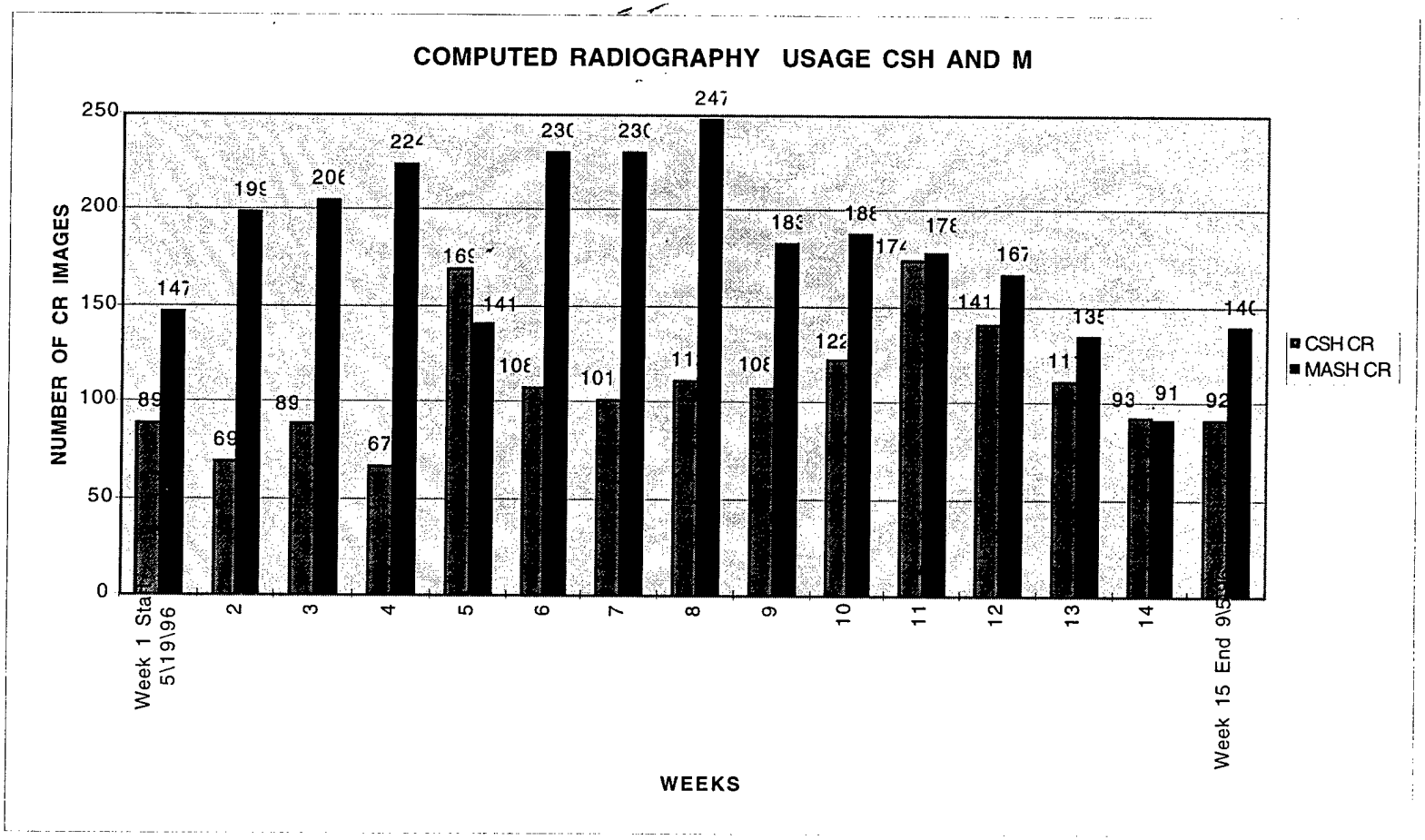
The success of the DEPRAD network is in part due to the use of the DICOM standard and the support of the vendors to work together towards developing a truly DICOM compatible teleradiology network. The continued usage of the network confirms that teleradiology has a real application to in military deployments. It can ensure high quality medical care while providing rapid and definitive response to trauma, even in those areas where there are no radiologists.

The logical extension of this deployment is to apply the knowledge gained to non-military applications. Since all commercial off the shelf components were used, this type of network could be recreated in a non-military environment. However, for a truly commercial application, further investigations are required in an automatic archive and connectivity to a Radiology or Hospital Information System (RIS/HIS) or computerized reporting system. These two items were not considered high priority for this deployment, but could be considered essential to a commercial application.

Phase II of this deployment is currently underway. Due to the success of Phase I, the military has decided to install phase II which provides laser film digitizers (LFD) and portable satellite terminals to 2 remote areas of Bosnia. This will allow the remote medical facilities to transmit film digitized images to the CSH, MASH, or LRMC for consultation and primary diagnosis. These images can also be transmitted, via the Internet or secure military network, to other military medical institutions throughout the U.S. and the world. The Phase II equipment has been tested and deployed, but operations have not begun yet.

DEPRAD was designed to be a low cost commercial off the shelf teleradiology system that the military could deploy in times of peace or war to any region of the world. The success of the Bosnia deployment has confirmed that teleradiology is a viable and valuable medical tool in a military medical environment, but can easily be extended to the civilian world of medicine.

Figure 6. Computed Radiography Usage at the CSH and MASH



1.2 Home Teleradiology Server (HOMERAD) with Modularity

Primary Investigators

Darmadi Komo, MS
Betty Levine, MS

ABSTRACT

Teleradiology will have a greater role in the military. Future teleradiology must use cost effective commercial software that can be configured to support greater modularity. A Home Teleradiology Server (HOMERAD) has been installed in Georgetown University Medical Center Department of Radiology that allows on-call physicians to view patients' images at home. Images from computer tomography, ultrasound, magnetic resonance imaging networks are sent to physicians' homes via a central server at the medical center. The server has a DICOM network agent that listens to DICOM messages from the modalities network and interpret them into separate DICOM files. The server also has a general purpose flexible scheduling software that can be configured to send files to users at certain times. The DICOM files are sent automatically to physicians' computers at home using high speed modems. All the transmissions occur in the background without human interaction. The client computers consists of high end workstations (PC, laptop, and Macintosh) that have DICOM compatible software to view the transmitted images. The HOMERAD system provides the military and civilian physicians a cost effective and convenient environment for viewing patients' images at home.

1.0 Objective

The main goal of this project is to provide as quickly as possible to attending radiologists and fellows the ability to review cross-sectional imaging cases performed after hours in the Radiology Department at Georgetown University Medical Center. The impetus behind this project was adverse patient outcomes that occurred in several cases due to inaccurate interpretations on the part of radiology residents covering the department after hours.

2.0 Hardware and Software Configurations

Macintosh:

- Power Mac 8500/120 MHz PowerPC
- 2 Gbytes hard disk
- 32 MB RAM
- 4X CDROM drive
- System 7.5.2 operating system
- SoftWindows 95
- NIH Image 1.6
- Store and Forward client
- 28.8 kbps modem
- 17" Applevision 1710 AV display monitor

Laptop PC:
- Dell Latitude 120 MHz Pentium
- 1.3 Gbytes hard disk
- 32 MB RAM
- Windows 95
- Osiris (modified version by Darmadi Komo)
- Store and Forward client
- 28.8 kbps modem
- External 17" Sony monitor 17sfII

PC Client:
- Pentium 133 MHz Micron
- 32 MB RAM
- 2 Gbytes hard disk
- 6X CDROM
- Iomega Ditto 3200 tape drive
- Windows 95
- Osiris (modified version by Darmadi Komo)
- Store and Forward client
- 28.8 kbps modem
- 17" Sony monitor sfII

Compaq PC Server:
- 90 MHz Intel Pentium system
- 16 MB RAM
- 1.4 Gbytes hard disk
- Ethernet card
- DICOM agent
- Store and Forward server
- Microsoft TCP/IP

3.0 Features

The whole system will have the following features:

- The system will have workstations that are either PC-based or Macintosh-based depending on the preference of the physician.

- Each faculty radiologist will receive a workstation to be located in the home which would be connected initially by a 28.8 kbps modem to a teleradiology server located at Georgetown University Medical Center.

- The fellows would receive a monitor to be placed in their home and a laptop computer will be passed from fellow to fellow depending on who is on-call. This laptop will be connected to the monitor to provide a teleradiology workstation for the fellow on-call.

- The system will have the feature that the technologists at the Medical Center will be able to forward the images to the attending physician's home without requiring the attending physician to manually initiate the transfer procedure. This will allow the images to be transferred while the physician is sleeping. Only waking the physician for the actual interpretation of the study.

- The system will be able to support full resolution images and lossless compression for transmission of images.

- In keeping with an open systems philosophy, all image transfers and image storage will be in the DICOM 3 format.

4.0 Implementation

- It was determined that a program called Store and Forward from Evergreen Systems could be used to perform the file transfers using either 28.8 kbps modems or ISDN should that become necessary. This program is very flexible especially with its scheduling module.

- A poll of the radiologists who might be receiving cross-sectional images either now or in the future revealed a total of 17 persons who might need to have systems. These included 12 people from Abdominal Imaging and Neuroradiology plus selected individuals in General Radiology, Fellows and one person from Interventional Radiology Five persons selected the Macintosh platform and the remainder chose Intel based PC's as the platform.

- Accordingly, two high performance laptop systems with 32 Megabytes of RAM and high speed video displays have been used. Five Macintosh Power Macintosh 8500 systems with 32 Megabytes of main memory have been used, and ten 133 MHz Pentium PC systems with 32 Megabytes of main memory and 4 Megabytes of VRAM have been used.

- The Store and Forward software and the upcoming SMS Radiology Information Systems software require a PC to perform. For this reason, the Macintosh platforms were fitted with a PC board containing a 486 processor and 16 Megabytes of memory to perform the file transfer functions and to communicate with the SMS system which is being currently implemented in the department.

- Initially the users were to be offered either software from NIH called NIH Image or software from the University of Geneva called OSIRIS for viewing the images.

- The original OSIRIS software as distributed by the University of Geneva contains some deficiencies such as being unable to read multiple images into a single viewing area for the convenience of the radiologist. The software as distributed requires the user to open each file individually rather than dragging across a number of files to open a large number of images simultaneously. The PC version of OSIRIS has been modified to allow multiple images to be opened with a single mouse movement. We are working on making the appropriate modification to Macintosh version. Additionally, the hardware PC board that was to be inserted in the Macintosh was determined to be faulty and the shipment of the board as planned for insertion into the Macintosh has been delayed. Thus, we are providing the Macintosh users with a emulation software called SoftWindows 95 that allows Macintosh to run Windows 95 and Windows 95 software. Macintosh users can choose between NIH Image or Osiris for viewing medical images.

- The Pentium based server for Teleradiology has been fully configured.

5.0 Future Implementation

At the present time only CT images can be transferred to the Pentium server for teleradiology as the CE CT scanners are the only ones capable of outputting DICOM files. In the future the AGFA and Siemens system will be able to export DICOM files to the Pentium server allowing teleradiology for ultrasound and MRI cases as well. There will be also an upgrade on the transmission media. Currently the modem with 28.8 kbps is sufficient in terms of the usage. In the future, we will upgrade the medium of transmission to higher capacity line such as ISDN or ADSL.

Akamai Annual Report

Chapter 2

Digital Imaging and Network Integration

2.1 Optimization of Wavelet Decomposition through Neural Network Search: Implication on Data Accuracy, Feature Preservation, and Compression

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ABSTRACT

Data compression has a critical role in the digital imaging network since it can reduce the data volulme and improve system performance. But data compression also imposes constraints in terms of accuary and feature preservation. This report addresses these competing factors in data compression. A neural network based framework has been developed to search for an optimal wavelet kernel that is most suitable for a specific image processing task. In this paper, we demonstrate that only the low-pass filter, h_u, is needed for orthonormal wavelet decomposition. A convolution neural network can be trained to obtain a wavelet that minimizes errors and maximizes compression efficiency for an image or a defined image pattern such as microcalcifications on mammograms. We have used this method to evaluate the performance of tap-4 orthonormal wavelets on mammograms, CTs, MRIs, and Lena image. We found that Daubechies' wavelet (or those wavelets possessing similar filtering characteristics) produces satisfactory compression efficiency with the smallest error using a global measure (e.g., mean-square-error). However, we found that Harr's wavelet produces the best results on sharp edges and low-noise smooth areas. We also found that a special wavelet, whose low-pass filter coefficients are (0.32252136, 0.85258927, 0.38458542, -0.14548269), can greatly preserve the microcalcification features such as signal-to-noise ratio during a course of compression. Several interesting wavelet filters (i.e., the *g* filters) were reviewed and explanations of the results are provided. We believe that this newly developed optimization method can be generalized to other image analysis applications where a wavelet decomposition is employed.

1.0 Introduction

In the field of transform coding, discrete cosine transform (DCT) based decomposition methods were developed extensively in 1970's and 1980's. Most of the techniques developed in this area are associated with block DCT[1-4]. However, several investigators indicated that the use of full-frame DCT[5-7] can produce high compression efficiency with high data fidelity and without blocky artifact. This method is particularly appropriate for high-resolution large-sized images. Recently, sub-band and wavelet transformations have been widely used in image compression research[8-10]. Unlike DCT, there exists many discrete wavelet transform (DWT) filters that can perform data decomposition. This paper provides a neural network approach to search for an optimal wavelet that minimizes quantization errors and at the same time produces the highest compression efficiency. This method can also be extended to evaluate various wavelets in preserving defined image features.

2.0 Algorithm Development

2.1. Construct a Neural Network using Wavelet Decomposition

The artificial neural network described in this paper is based on the convolution process which is used in the sub-band including wavelet decomposition. In fact, the wavelet-based neural network performs exactly the same as the conventional wavelet transform. Our approach is to use the training capability of the neural network to obtain the most suitable wavelet kernel for a specific signal processing task[11]. In this paper, our task is to minimize error and simultaneously achieve the highest compression efficiency during the course of compression and decompression processes. In order to match the sub-band decomposition, several characteristics of the neural network must be established: (a) no hidden but one output layer is used, (b) local connection through convolution process rather than fully connected nets is employed, and (c) the convolution process must be inversible (wavelet kernels are used in this paper). During compression and decompression processes, the inversible process is approximately conducted. The approximation is not due to the inverse transformation but because the inaccuracy of the quantized transform coefficients. Figure 1 shows the structure of the neural network using quantized transform coefficients as the targets.

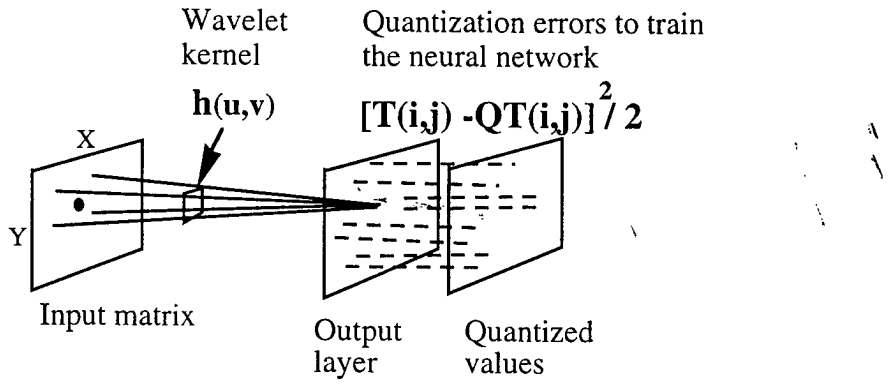

Figure 1. A neural network based on wavelet decomposition and trained by quantization errors. T(i,j) and QT(i,j) denote transform and quantized coefficients in high-frequency domains, respectively.

In fact, we should not consider only the issue regarding minimization of quantization errors. The minimization of entropy must also be taken into account for the optimization. We combine both issues by multiplying the mean-square-error function with an imposed entropy reduction function. The cost (error) function for training the neural network becomes

$$Ef(i,j) = Z(QT(i,j)) \times [T(i,j) - QT(i,j)]^2 / 2 \qquad ...(1)$$

where $QT(i,j)$ is the quantized transform coefficient at pixel (i,j) and $Z(QT(i,j))$, which is the entropy reduction function for a set of quantization coefficients, is given below:

$$Z(QT(i,j)) = \begin{cases} 0 & for \quad QT(i,j) = 0 \\ 1 & for \quad |QT(i,j)| = 1 \\ F(n,q) & for \quad |QT(i,j)| = n. \end{cases} \qquad ...(2)$$

$F(n,q)$, *which* is a ramp function, is a function of quantization factor, q, and is somewhat inversely proportional to the quantized integer, n. The value of the ramp function should always be smaller than 1.

The reason to design the entropy reduction function for a fixed quantizer, q, using eq. (2) is three-fold: (a) since most low value coefficients (-0.5q < T(i,j) < 0.5q) are associated with noise when q is not a very large value, there is no need to emit error from the output node possessing quantized value 0 to train the neural net; (b) the more the low quantized values are, the lower the assemble entropy will be; and (c) the probability to turn a high quantized value into a low quantized value is very low, therefore errors backpropagated from high quantized values should be less emphasized as compared to low quantized values 1, 2, or so. When q is very small, the quantization error is in the range of global image noise. In this case, the neural network will rely on the guidance of Z function to search for a wavelet filter that produces more low transform values. The success of this cost (error) function design is depicted in our experiment shown in the Results Section.

Based on the neural network shown in Figure 1, we can train the convolution kernel. The specific training algorithm is given in Section 2.2. Unfortunately, the neural network suggested kernel may not be a wavelet kernel. Section 2.4 shows a method to conduct wavelet decomposition without using the high-pass filter. Hence, the low-pass filter is the only kernel to process the 4 channels for two-dimensional (2-D) wavelet decomposition. Section 2.5 provides algorithms that will modify the kernel to fulfill the requirements of wavelet kernel. Through this process, we can find a wavelet that produces the lowest quantization errors with the lowest entropy of the quantized transform coefficients.

2.2. Signal Propagation through Convolution Process and Methods for Training the Neural Network

The signal propagation from input layer to output layer involving convolution computation is given below:

$$T_c(i,j) = K_c(u,v) \otimes S(i,j) \qquad ...(3)$$

where S(i,j) is the original image, subscript c denotes the channel number, and $K_c(u,v)$ is the convolution kernel for channel c. For the wavelet decomposition, the relationship between $K_c(u,v)$ and the wavelet filters (i.e., h and g filters) will be given in Sections 2.3 and 2.4.

Since we treat the wavelet transform as a locally connected neural network, the well-known backpropagation (BP) training method can be used to train the weights (kernel) in each epoch[12]. Note that a linear function instead of a typical sigmoid function for a conventional neural network system is used in this process. The updated kernel suggested by backpropagation in the neural network is given by

$$K_c(u,v)[t+1] = K_c(u,v)[t] + \eta \sum_{i,j} \delta(i,j) S(i-u, j-v) + \alpha \Delta K_c(u,v)[t] \qquad ...(4)$$

where t is the iteration number during the training, α is the gain for the momentum term received in the previous learning loop, η is the gain for the current weight changes, and δ is the weight-update function which is given by

$$\delta(i,j) = \frac{\partial Ef}{\partial K_c(u,v)} . \qquad ...(5)$$

2.3. Two-Dimensional Wavelet Decomposition

Following Mallat's 2-D wavelet analysis[9], the two-dimensional scaling function is composed of two one-dimensional scaling functions in both directions:

$$\phi(x,y) = \phi(x)\phi(y) \qquad ...(6)$$

where $\phi(x)$ is a scaling function. The associated two-dimensional wavelets are defined as

$$\psi^H(x,y) = \phi(x)\psi(y) \quad ...(7)$$

$$\psi^V(x,y) = \psi(x)\phi(y) \quad ...(8)$$

$$\psi^D(x,y) = \psi(x)\psi(y) \quad ...(9)$$

where $\psi(x)$ is the 1-D wavelet corresponding to the 1-D scaling function. Using the sub-band coding algorithm, the wavelet transform (2-D DWT) of a matrix has four parts:

$$W_{LL}(f(x,y)) = \sum_{u,v}[(f(x,y)h(u-2x,0))h(0,v-2y)] = \sum_{u,v}[f(x,y)h_{LL}(u-2x,v-2y)] \quad ...(10)$$

$$W_{LH}(f(x,y)) = \sum_{u,v}[(f(x,y)h(u-2x,0))g(0,v-2y)] = \sum_{u,v}[f(x,y)h_{LH}(u-2x,v-2y)] \quad ...(11)$$

$$W_{HL}(f(x,y)) = \sum_{u,v}[(f(x,y)g(u-2x,0))h(0,v-2y)] = \sum_{u,v}[f(x,y)h_{HL}(u-2x,v-2y)] \quad ...(12)$$

$$W_{HH}(f(x,y)) = \sum_{u,v}[(f(x,y)g(u-2x,0))g(0,v-2y)] = \sum_{u,v}[f(x,y)h_{HH}(u-2x,v-2y)] \quad ...(13)$$

where h and g functions are the low and high pass filters of the sub-band decomposition with condition $g(u) = (-1)^u h(1-u)$. The low pass filter, h, also must satisfy three criteria to construct the orthonormal basis of compactly supported wavelets[5,6]: (Note that we also use g_u and h_u to replace $g(u)$ and $h(u)$, respectively, for simplicity in this paper.)

(a) $$\left[\sum_u h_{2u}\right] - \sqrt{2}/2 = \left[\sum_u h_{2u+1}\right] - \sqrt{2}/2 = 0; \quad ...(14)$$

(b) should be orthonormal; this means that

$$\left[\sum_u h_u \times h_{u+2n}\right] - \delta_{u,u+2n} = 0 \quad ...(15)$$

where $o_{i,j}$ is Dirac delta function and n is an integer; and

(c) have a high degree of regularity.

From the compression perspectives, the above constraints are very limited. For a lossless compression, those filers performing perfect reconstruction are illegible. However, we would like to focus our view on using wavelet transform in this paper.

The 2-D filters at the second forms of eqs. (10-13) are the vector products of h and/or g filters. The relationship between high pass and low pass filters make the unification of the four sets of decomposition possible as shown in section 2.4.

According to the wavelet theory, it is known that given a set of h, one can calculate the Fourier transform of the scaling and wavelet functions as follows:

$$\Phi(w) = H_0(e^{iw/2})\Phi(w/2) \quad ...(16)$$

$$\Psi(w) = H_1(e^{iw/2})\Phi(w/2) \quad ...(17)$$

where $H0$ and $H1$ are Fourier transforms of h and g filters, respectively. Hence, both the scaling and wavelet functions can be obtained through infinite recursion by using eqs. (16) and (17), respectively.

2.4. Unification of the Four Channels Decomposition in 2-D DWT

Using Eq. (11) as an example to rewrite the decomposition equation by replacing the g with the h filter, we have:

$$W_{LH}(f(x,y)) = \sum_{u,v}\left[(f(x,y)h(u-2x,0))(-1)^v h(0,2y+1-v)\right] \quad ...(18)$$

or

$$W_{LH}(f(x,y)) = \sum_{u,v}\left[(((-1)^v f(x,-y))h(u-2x,0))h(0,v-2y)\right]$$

$$= \sum_{u,v}\left[(((-1)^v f(x,-y))h_{LL}(u-2x,v-2y)\right] = \sum_{u,v}\left[f_{LH}(x,y)h_{LL}(u-2x,v-2y)\right]. \quad ...(19)$$

Converting Eq. (14) to use the 2-D low pass filter as the kernel is a matter of changing the orientation from y- to x-direction (or combining both directions for Eq. (15)). These conversions also indicate that one can use a single 2-D filter to compute the four quadrants of the 2-D wavelet transform by flipping the matrix position in x- and/or y-direction(s) and alternating the sign of the flipped matrix corresponding to the direction(s).

The alternated sign of the source vector makes the convolution operation unconventional. A precalculation method, that involves a cross product of two vectors, can be employed: flipping data sequence of an image is the first vector and the second vector is fixed and composed of +1 and -1. An example of 1-D precalculation steps for tap-6 kernel prior to the convolution operation is given below:

Original data sequence: $a_1, a_2, a_3, a_4, a_5, a_6$

Flipped data sequence: $a_6, a_5, a_4, a_3, a_2, a_1$

Resultant data sequence: $a_6, -a_5, a_4, -a_3, a_2, -a_1$

In the case of 2-D, three matrices associated with horizontal, vertical, and diagonal decomposition for the second matrix in precalculation are given below in Figure 2. With this precalculation (or cross product of two matrices), only the low-pass filter $h_u h_v$ (h_u in 1-D) is needed for the final wavelet transform operation.

$$\begin{bmatrix} + & + & + & + & + & + \\ - & - & - & - & - & - \\ + & + & + & + & + & + \\ - & - & - & - & - & - \\ + & + & + & + & + & + \\ - & - & - & - & - & - \end{bmatrix}$$

Vertical operator

$$\begin{bmatrix} + & - & + & - & + & - \\ + & - & + & - & + & - \\ + & - & + & - & + & - \\ + & - & + & - & + & - \\ + & - & + & - & + & - \\ + & - & + & - & + & - \end{bmatrix}$$

Horizontal operator

$$\begin{bmatrix} + & - & + & - & + & - \\ - & + & - & + & - & + \\ + & - & + & - & + & - \\ - & + & - & + & - & + \\ + & - & + & - & + & - \\ - & + & - & + & - & + \end{bmatrix}$$

Diagonal operator

Figure 2. Three matrices used for the cross product precalculation.

Nevertheless the resultant matrix of this precalculation (or cross product of two matrices) must be held in the computer memory to facilitate the computation for forward convolution and the corresponding backpropagation. After precalculation, the size of the intermediate images is ($k/2 \times k/2$) times the original image size. The factor of $1/2 \times 1/2$ is due to the 1/2 down sampling two-dimensionally in a conventional forward wavelet transform. The largest three blocks shown in Figure 3 are the intermediate images $S_O(xk/2, yk/2)$.

One of the original criteria regarding the so-called "high degree of regularity" was not enforced in the algorithm. The orthonormality of the h_u filter may not be self-sustained with each updated version. However, some small modification is possible to make the final version of h_u orthonormal, if the conditions of being a wavelet filter set are to be fully met. Based on each precalculated image $S_O(xk/2,yk/2)$ described earlier, Eq. (4) can be rewritten for updating 2-D wavelet kernel

$$K(u,v)[t+1] = K(u,v)[t] + \eta \sum_{i,j} \delta(i,j) S_0(xk/2 - u, yk/2 - v) + \alpha \Delta K(u,v)[t] \qquad ...(20)$$

where index i = 0,1,...$(k\text{-}1)^2$ corresponds to the sub-image of S_o matched to the kernel size. Eq. (20) represents the updated kernel suggested by the BP, these values require a conversion to a new wavelet kernel $h'_u h'_v$. Assuming the wavelet filter is a 2-D vector (i.e., $h_u h_v = h_v h_u = h_{LL}$, where $u\&v$ = 0,1,2, ... k-1), then only k free parameters ought to be trained for a wavelet transform. A solution to satisfy the wavelet constraints and to make $h'_u h'_v$ approximately equal to $K'(u,v)$ is given in section 2.5.

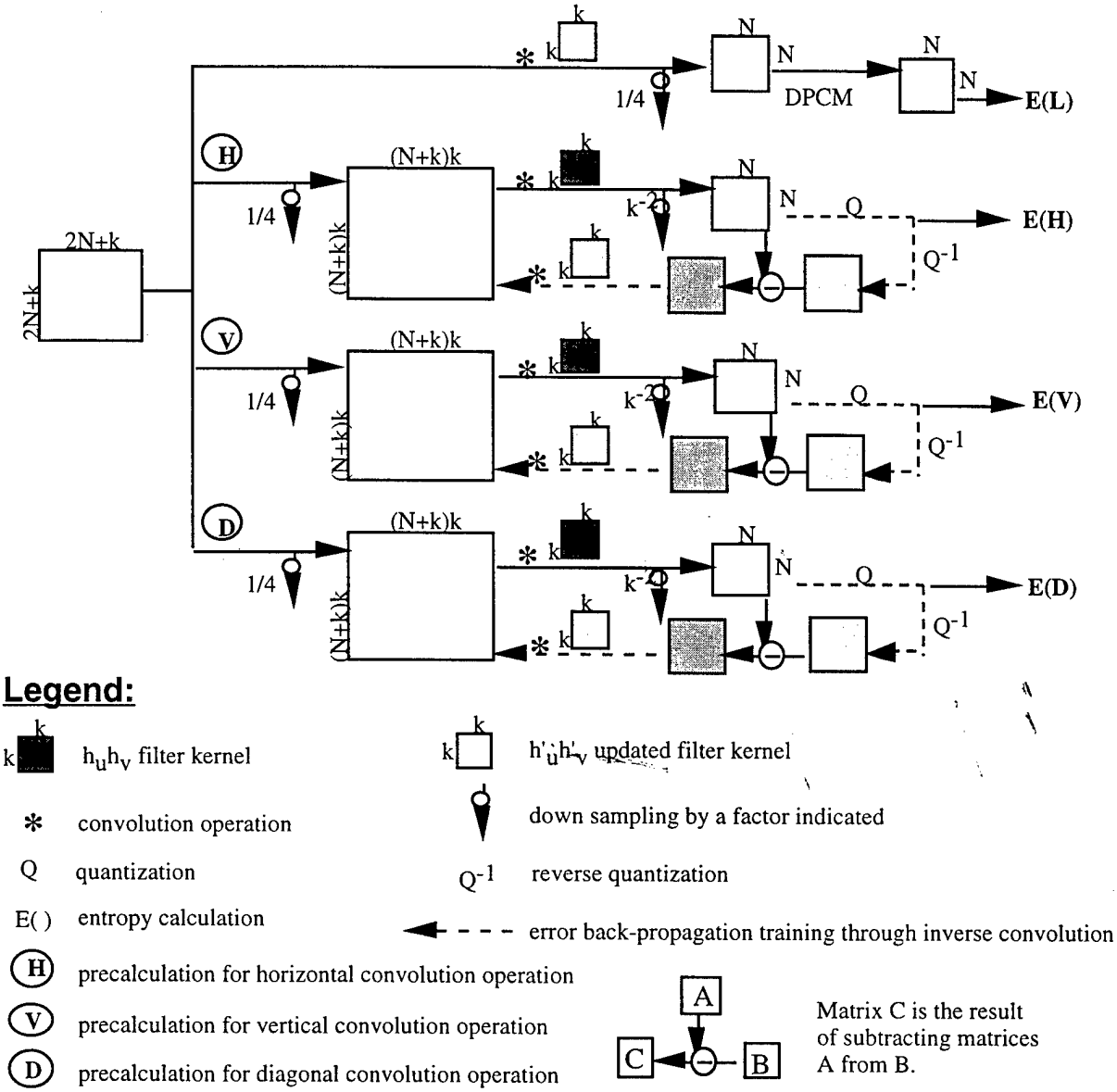

Figure 3. A proposed training scheme based on a grouped (kernel) backpropagation neural network to obtain an optimal orthonormal kernel for image compression.

2.5. Converting Neural Network Suggested Kernel to Fulfill Requirements of a Wavelet Filter

As indicated in Eq. (20), the updated weights, $K(u,v)[t+1]$ or $K'(u,v)$ of the kernel suggested by the BP at $t+1$ training iteration are independent. One must realize that each epoch in the neural network training is only a suggestion or approximation that the changes of weights may produce a lower value for the defined error function, Ef. To properly use this suggestion for making a new wavelet kernel, let's assume that there exists a set of h'_u so that the updated 2-D version of the wavelet filter is very close to $K'(u,v)$. A function based on the square difference is used in the derivation

$$f(h'_u) = \sum_{u,v} (h'_u h'_v - K(u,v))^2. \qquad ...(21)$$

Here we intend to minimize the function, f, subject to the constraints equations. Lagrangian multiplier method can be employed to solve this problem by combining f and constraint equations:

$$df(h'_u) + \sum_p \lambda_p dC_p(h'_u) = 0 \qquad ...(22)$$

where d represents the differentiation operation of a function and λ_p is the Lagrangian multiplier for the corresponding constraint equation, $C_p(h'_u) = 0$, referred to eqs. (14) and (15). Using this approach we can obtain a set of h'_u while f is also minimized.

3.0 Materials and Experimental Methods

A database consisting of 45 mammograms was used to conduct the study. Of these mammograms, 38 contain biopsy proven clustered microcalcifications. A total of 220 microcalcifications are embedded in 41 clusters. All 45 mammograms were digitized by a LumyScan (model 150) film digitizer with spot size of 100μm. Each patch of 32×32 pixels (i.e., an area of 3.2×3.2 mm^2) with its center at the peak value was isolated for the study of quantization impact on microcalcifications. The process of searching optimal wavelet kernels for original mammograms and microcalcification patches were conducted. Each image was decomposed by 3-level wavelet transform. Quantization values were q, q/2, and q/4 for decomposition of high frequency coefficients on levels 1, 2, and 3, respectively. For each training epoch, the mean-square-error (MSE) and %zeros (i.e., number of zeros / total number of pixels) were computed. Since %zeros generally contributes the most important factor to gain a compression, it can be used as a coarse index for the evaluation of compression efficiency for each epoch.

In order to demonstrate each wavelet performance, we sorted the first coefficient h_0 of the low-pass filter associated with the mother scale function as the horizontal scale because the training epoch does not represent the wavelet being used as shown in Figures 6 and 7. All h_0 values are greater than -0.1464466094 and smaller than 0.85255533905. The corresponding h_1 values are greater than 0.35355339 and smaller than 0.85255533905. Those h_1 values, which are greater than -0.1464466094 and smaller than 0.35355339, have corresponding conjugate values in the former set and can be ignored.

Compression ratios were calculated only when the neural network search had been successful. The spatial and temporal correlation of quantized coefficients were taken into account but might not be optimized. Specifically, we arranged quantized coefficients from one pixel of the highest level to the corresponding 4 pixels on the second highest level to 16 pixels on the lowest level and then went back to the next pixel of the highest level and so on. This rearranged data sequence is more correlated in a spatial-temporal sense[13] and can be encoded effectively by Lempel-Ziv coding[14].

We have also performed the same study for the isolated 220 microcalcification patches. The 2-D profiles of microcalcifications and their nearby areas (i.e., the areas that are not included in the microcalcification profile but within the isolated block 32×32 pixels) were evaluated separately during the course of the neural network search. In addition, features of the microcalcifications were computed to observe their changes. These features of microcalcification are:

(a) the peak value, P;

(b) the contrast, C = P-b;
where b is the average background value which is the immediate boundary of the microcalcification profile;

(c) the signal-to-noise-ratio, SNR = C/SD_b;
where SD_b stands for the standard deviation of the background; and

(d) the area occupied by the 2-D microcalcification profile, A.

4.0 Results

In the neural network training, the MSE is not the only factor concerned; the entropy reduction function is another factor that drives the neural network to perform a search. In the first neural network experiment, we found that the MSE changes very little with a low quantization factor (q=16). The neural network movement in searching for the next wavelet kernel was random, and no minimum of MSE could be found in the mammogram study. However, the %zeros changed, which led the neural network to converge at the maximum value of %zeros. When a larger quantization factor (q=64) was used, the MSE seemed to function in training the neural network. Figures 4 and 5 show the curves of MSEs and %zeros against the sorted h_0 values. In both figures, Daubechies' (h_0 = 0.48296291) and its nearby wavelets perform the highest %zeros implying the largest compression ratio.

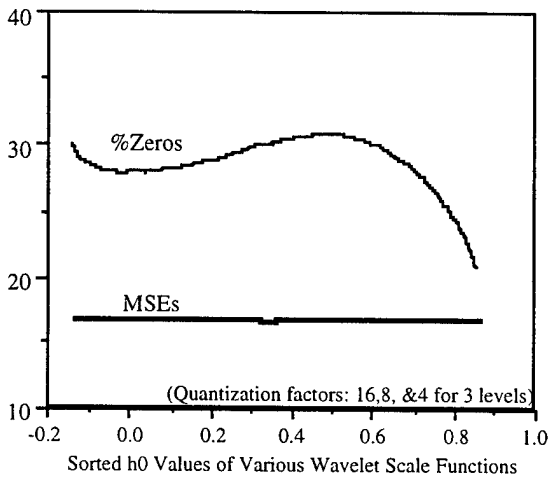

Figure 4. Decomposition Performance of Wavelets on Mammograms (q=16).

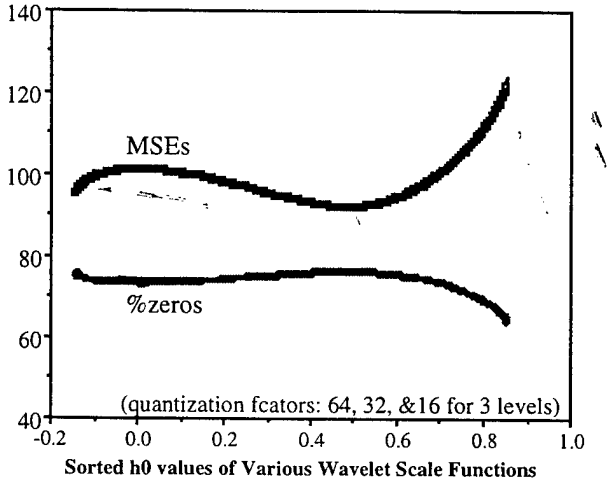

Figure 5. Decomposition Performance of Wavelets on Mammograms (q=64).

In the microcalcification study, we found that %zeros does not change much until $h_0 > 0.6$. Figure 6 shows the original learning steps which drive MSEs into lower values using the proposed neural network training mechanism. Figure 7, which is a sorted version of Figure 6 (same sorting processes were applied to all figures in this section), shows that Daubechies' wavelets perform the lowest MSEs. More specifically, microcalcification profiles suffered higher MSEs than their background areas as indicated in Figure 8.

These results were altered when a very large quantization factor was used. In Figure 9, all the microcalcification patches were rounded-off to 8-bit prior to the study which assumed digitized mammograms containing about 4-bit of noise[15]. Although the largest quantization factor was 16 for 8-bit mammograms, the effective quantization factor was equivalent to ≈256 in 12-bit mammograms. Figure 9 shows that Harr's wavelet (h_0 = 0.0) performs a high and the lowest MSEs for 2-D microcalcification profiles and their background, respectively. However, Daubechies' wavelets

perform in an opposite way. This is probably because Harr's wavelet can produce a lower entropy for low-noise smooth areas.

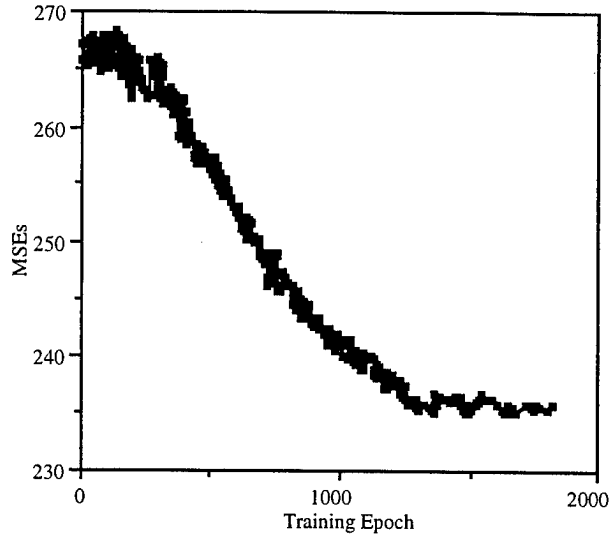

Figure 6. MSEs were Decreased During the Training of the Neural Network on 220 Microcalcifications (q=64).

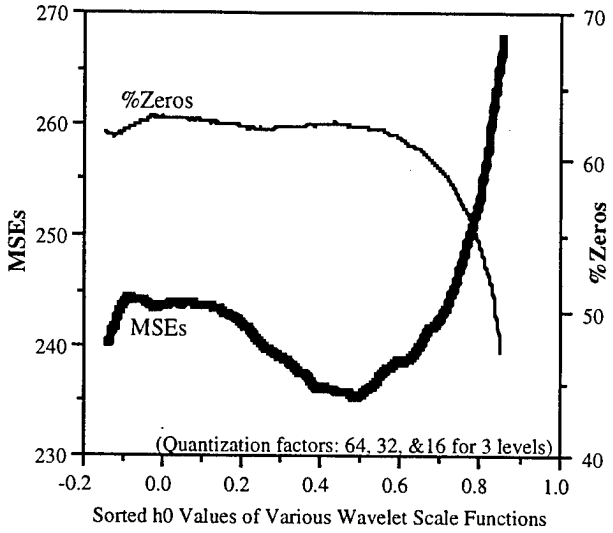

Figure 7. Decomposition Performance of Wavelets on 220 Microcalcifications (q=64).

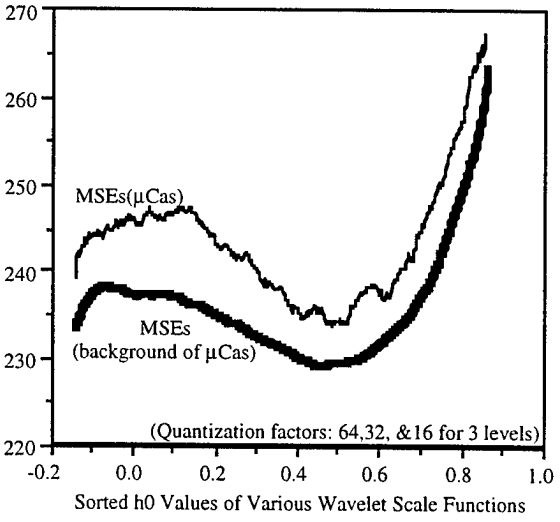

Figure 8. Decomposition Performance of Wavelets on 220 Microcalcification Profiles and Background (q=64).

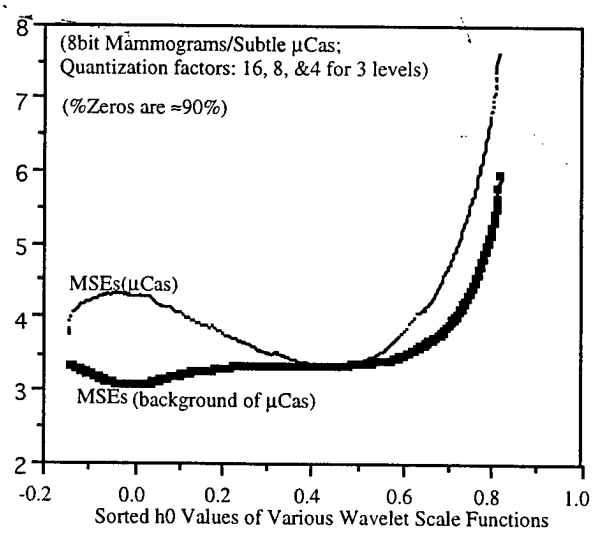

Figure 9. Decomposition Performance of Wavelets on 220 Microcalcification Profiles and Background (8-bit, q=16).

The results of the microcalcification evaluation study based on quantized wavelet coefficients are shown in Figures 10-13. In fact, the evaluation was performed with an identical experimental condition as that in Figure 9. However, microcalcification features were measured instead of MSEs and %zeros. Note that % number decrease in peak values, contrast, and SNR were shown in negative values. In other words, the lower the % number decrease value is, the more microcalcifications involving negative changes. The figure of merit (FOM) for each measure was a composed value given by

FOM = (%No. decrease × % decrease + %No. increase × % increase) × 100. ...(23)

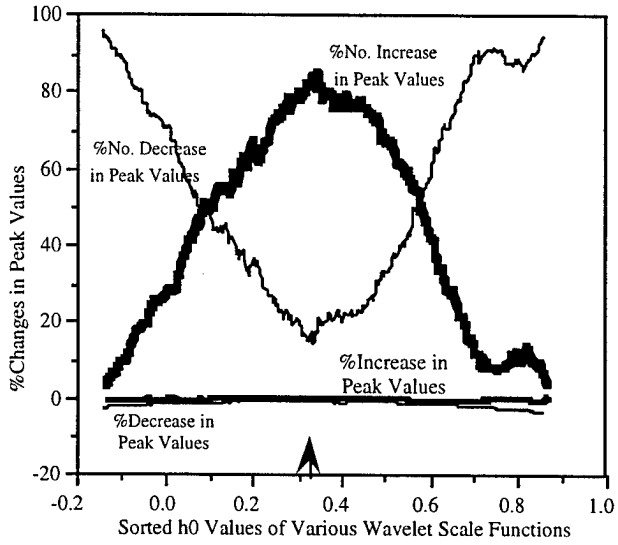

Figure 10. Peak Values Changes Due to Quantization Effects on Wavelet Domain for Microcalcifications.

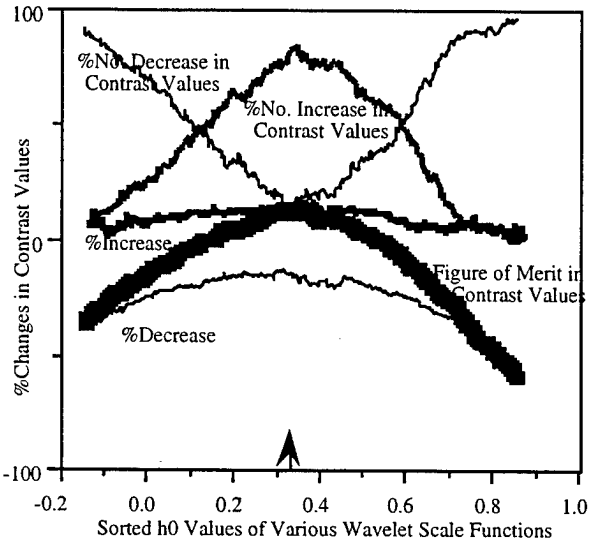

Figure 11. Contrast Changes Due to Quantization Effects on Wavelet Domain for Microcalcifications.

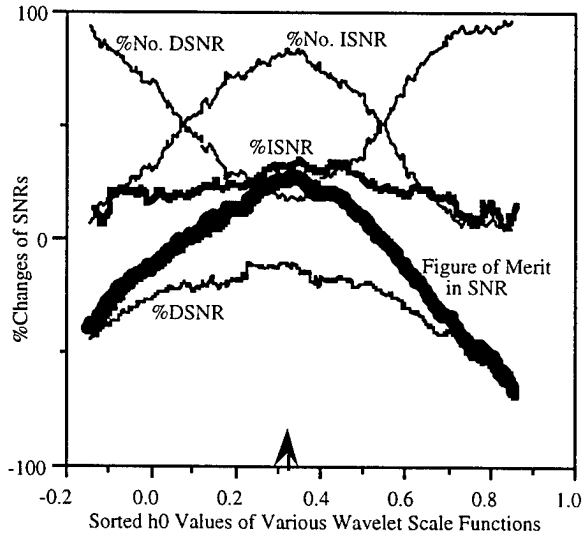

Figure 12. SNR Changes Due to Quantization Effects on on Wavelet Domain for Microcalcifications.

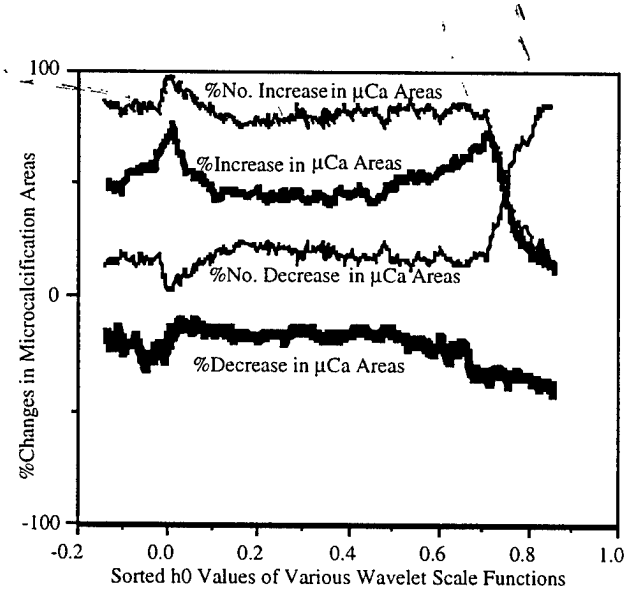

Figure 13. Areas of Microcalcification Profile Changes Due to Quantization Effects on Wavelet Domain.

As indicated in Figure 10, the peak values were changed very little. However, % number increases in peak values, contrast values, and SNRs of microcalcifications had about the same distribution in Figures 10, 11, and 12. The highest FOMs in all three measures were at the wavelet with the low-pass filter coefficients: (0.32252136, 0.85258927, 0.38458542, -0.14548269) which is marked with an arrow sign in the Figures. Figure 13 shows minor %area changes of microcalcification profiles from 0.2 to 0.6 of h_0 values. These effects were not observed when a low quantization factor was used.

5.0 Discussion

After observing these results, one may still be confused about what was going on. The authors would like to provide some explanations in the following discussion. Let's start with graphics of the low-pass *h* and the high-pass *g* filters for several interesting wavelets mentioned in the Results Section. Figures 14 and 15 show the h and g filters, respectively. Note that the X wavelet is the same wavelet marked on the horizontal axis in Figures 10, 11, and 12. One should pay more attention to the graphics of the *g* filters, since they produce high frequency coefficients for quantization. We can deem that *g* filter essentially performs calculation involving the positive weight multiplied by the center pixel value plus the adjacent pixel values on the two sides multiplied by the negative weights of the *g* filter. Daubechies' wavelet has quite balanced negative terms at the two sides of the positive weight and the sum of negative weights is negatively equal to the positive weight. The latter is a constraint in all wavelet filters anyway. In addition, the absolute value of *g1(=-h2)* or *g2 (=h1)* should be reasonably large, which would maintain the low-pass and the high-pass characteristics for *h* and *g* filters, respectively. In fact, those wavelets near Daubechies' wavelet including the one (X wavelet) with the highest performance in microcalcification features possess this property. From the signal processing point of view, these balanced weights in a filter are very important characteristics to create low entropy values for general textures. We suspect that this property may have something to do with the so called "high regularity" in the wavelet theory.

In short, we found that the main reason that a wavelet filter can produce a low entropy for a set of data is because the weight sum of the *g* filter is zero. For a general data sequence, the *g* filter can perform even better when

(a) the absolute value of *g1(=-h2)* or *g2(=h1)* is much larger than that of other weights.
(b) the opposite signed weights are evenly distributed at the two sides of *g1* or *g2*.

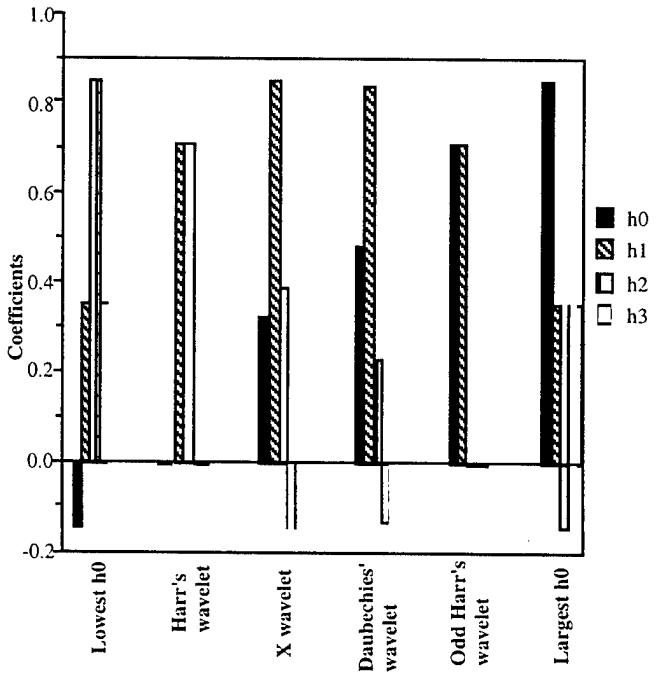

Figure 14. Low-pass Filters of Several Interesting Wavelets.

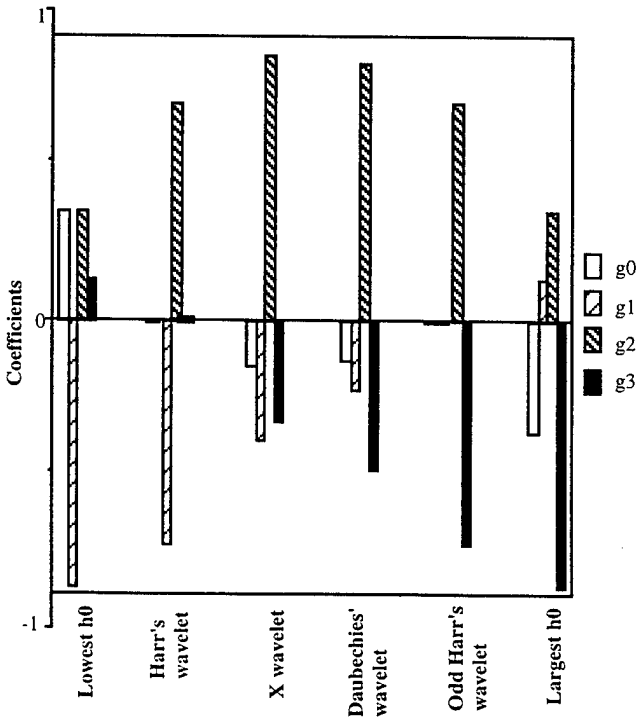

Figure 15. High-pass Filters of the Same Wavelets.

For low-noise smooth signals, Harr's wavelet may slightly outperform the others. For sharp edges, Harr's wavelet would greatly outperform the others, as depicted in Figure 16 where only bones as well as edges between bones and soft tissues isolated on computed tomographic (CT) images were the subjects for the evaluation.

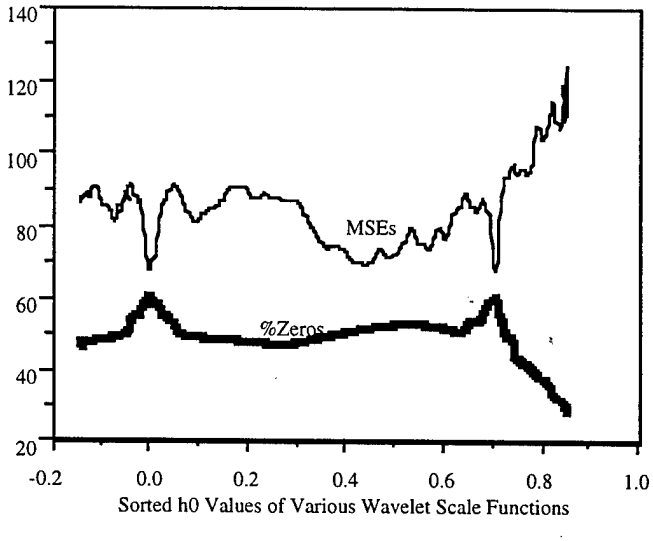

Figure 16. Decomposition Performance of Wavelets on CT Head Bones and Bone Edges (q=64).

We still do not quite understand why the wavelet possessing low-pass filter (0.32252136, 0.85258927, 0.38458542, -0.14548269) resulted in the highest feature preservation. However, Figure 9 has provided clues as to where MSEs of 2-D microcalcification profiles and background gradually merge from Harr's to Daubechies' wavelets. Since contrast and SNR values are computed using the peak and background values of the microcalcifications, the optimization of these measures should occur somewhere between Harr's and Daubechies' wavelets.

In the field of compression, it is known that the higher the compression ratio is, the higher the error that will be generated in the decompressed image. However, through these studies we discovered a new phenomenon associated with these two main quantitative measures in compression. We found that higher compression coincided with less error in all the studies (see Figures 4, 5, 7, & 16) using a fixed quantizer. This may be because high compression is associated with low entropy, which means that the data contains more low values and less variation between the originally transformed and quantized coefficients. This phenomenon happens only when the quantization factor is fixed. We would like to call for the reader's attention to the link between this phenomenon and the designed error function that comprises MSE and entropy reduction terms for training the convolution neural network. With this concurrent trend (i.e., less error is associated with low entropy using a fixed quantizer), the neural network can be effectively trained. Otherwise they would have functioned as competing factors and would have made the training of the neural network difficult.

Although we have shown the general framework of a wavelet filter search using a neural network training method, only tap-4 wavelet spectra were employed in our experiment. The above research findings seem able to be generalized for high order wavelets because the *g* filter is the key operator for the wavelet decomposition. The distribution of weights for high order wavelets should be maintained as discussed above in order to obtain a low entropy. We will continue to investigate the performance of bi-

orthonormal wavelets where an odd number of weights are used. We predict that high performance wavelets in compression and data accuracy should possess balanced distribution of weights in the *g* filter of bi-orthonormal wavelets.

In our previous papers, we indicated that wavelet (both orthonormal and bi-orthonormal) decomposition might be appropriate for low resolution small images such as the Lena image, CTs and MRIs. For high resolution large images such as digitized chest radiographs and mammograms, we found that the full-frame DCT performed with the highest compression efficiency[16]. This is because the DCT can pack highly correlated image information in a small frequency area. The DWT, however, requires many levels in decomposition to achieve a high compression ratio. The data inaccuracy would propagate from high level wavelet domains to low level and to the reconstructed image.

6.0 Conclusions

A neural network based method has been developed to search for optimal wavelet kernels which can produce the most favorable set of transform coefficients to preserve data accuracy and/or defined image features during the compression. In this paper, our technical achievements are: (a) development of a unified method to facilitate multichannel wavelet decomposition; (b) designing a cost (error) function consisting of MSE and imposed entropy reduction function for training the convolution neural network; and (c) converting neural network suggested kernel into a filter constrained by the wavelet requirements.

In all medical image modalities we have tested so far (including mammography, CT, MRI), Daubechies' wavelet (or its nearby wavelets) generally performs better (in most cases slightly better) than other wavelets for image compression using a global measure. With a large quantization factor, Harr's wavelet produces the lowest and highest MSEs for the background and microcalcification profile areas, respectively. However, Daubechies' wavelet produces an opposite result. In addition, we found that the wavelet associated with a low-pass filter, (0.32252136, 0.85258927, 0.38458542, -0.14548269), possesses the highest feature preservation capability in microcalcification peak, contrast, and SNR. Through this study, we also found that only Harr's wavelet sometimes produced a dramatic result, usually optimization occurs on a band of wavelets not at a single wavelet.

We, therefore, conclude that Daubechies' wavelet (and its nearby wavelets) is generally applicable for image compression. However, Harr's wavelet is suitable for low-noise smooth areas and sharp edges. For a specific image pattern such as microcalcifications on mammograms, one might find a wavelet filter can most preserve the features.

By reviewing the *g* filters of various wavelets, we found those optimal wavelets for general image texture have something in common. They possess balanced negative terms at the two sides of the positive weight and the absolute value of *g1* or *g2* is much larger than that of the other weights.

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2.2 The Lung Contour Detection in Chest Radiographs using a Convolution Neural Network

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ABSTRACT

Image processing is a core technology that enables a teleradiology and digital imaging network. The purposes of this research are to investigate the effectiveness of our novel lung contour detection method in chest radiographs and to develop an automatic computerized system for image processing. A total of 85 screening chest radiographs from Johns Hopkins University Hospital were digitized to 2K by 2.5K pixels with 12-bit gray scale. To reduce the amount of information, the images were smoothed and subsampled to 256 by 310 pixels with 8-bit. The detection approach consists of two one-dimensional convolution neural networks for the two direction profiles and postprocessing. Fourteen images were used for the training of the neural network and the remaining 71 images for testing. The postprocessing is the binarization followed by the morphological filtering. The algorithm can detect the lung contour at 82% accuracy against test images following the same rules as for the training images.

1.0 Introduction

Chest radiography is one of the primary and most widely used techniques in diagnostic imaging. Nowadays with the advent of digital radiology, the digital medical image processing techniques for digital chest radiographs have attracted considerable attention, and several studies on computer-aided diagnosis (CADx) as well as on conventional image processing techniques for chest radiographs have been reported [1-6]. In the automatic diagnostic process for chest radiographs, it is important to outline the areas of the lungs, the heart, and the diaphragm. This is because the original chest radiograph is composed of important anatomic structures and, without knowing exact positions of the organs, the automatic diagnosis may result in unexpected detections.

The automatic extraction of an anatomical structure from digital chest radiographs can be a useful tool for (1) the evaluation of heart size, (2) automatic detection of interstitial lung disease, (3) automatic detection of lung nodules, and (4) data compression, etc. Based on the clearly defined boundaries of heart size, rib space, rib positions, and rib cage extracted, one should be able to use this information to facilitate the tasks of the CADx on chest radiographs. In this paper, we present an automatic scheme for detection of lung contour from chest radiographs by using a shift-invariant convolution neural network [1].

2.0 Materials and Method

A schematic diagram of our method is shown in Figure 1. It consists of three sections: shrinking, processing by using the shift-invariant neural network [7-9], and postprocessing. First, in order to reduce the amount of information, the images were smoothed and subsampled to 256 by 310 pixels with 8-bit. Secondly, every profile extracted from the shrunk image is processed by trained neural networks. A whole image

is reconstructed with the output of its profiles. There are two neural networks for both the horizontal profile and the vertical profile. Finally each reconstructed images from two neural networks are combined and binarized. After binarization, the filter processes are applied to the binary image to get the final contour.

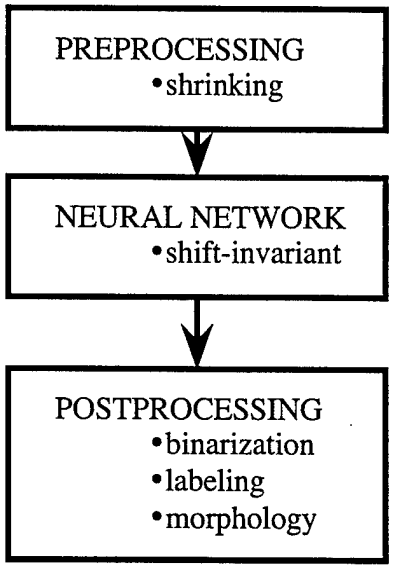

Figure 1. The schematic diagram of the lung detection method.

2.1 Acquisition of digital chest radiographs

A total of 85 screening chest radiographs from Johns Hopkins University Hospital were digitized to 2K by 2.5K pixels with 12-bit gray scale using a Lumisys laser scanner. To reduce the amount of information, the images were smoothed and subsampled to 256 by 310 pixels with 8-bit. The kernel used for smoothing was 8 by 8 pixels which is identical to 1.4 by 1.4mm physical size. Although this reduction was basically done for the computational limitation, this range of spatial resolution is enough for the anatomic based image processing which is our final purpose.

2.2 Extraction of the profiles

Let $I[x,y]$ denote the pixel value of the shrunk image at (x,y), where $0 \le x \le N-1, 0 \le y \le M-1$. N is the number of columns and M is the number of rows. Since the pixel value $I[x,y]$ represents an inverse of film density, the higher the film density, the lower the pixel value. The horizontal profile $Pi[x]$ and the vertical profile $Qj[y]$ are defined by

$$Pi[x] = I[x,i], 0 \le i \le M-1, 0 \le x \le N-1, \quad (1)$$

$$Qj[y] = I[j,y], 0 \le j \le N-1, 0 \le y \le M-1, \quad (2),$$

respectively. The horizontal profile $Pi[x]$ is the input data for the horizontal direction neural network. The vertical profile $Qj[y]$ is the input data for the vertical direction neural network.

2.3. Convolution neural networks

The shift-invariant neural network with two hidden layers is shown in Figure 2. The network model is a multi-layered feed-forward network which consists of neuron-like units with semi-linear activation function, namely a sigmoid function. Units in a single layer are divided into clusters. Each unit in the higher layer is connected to several units in

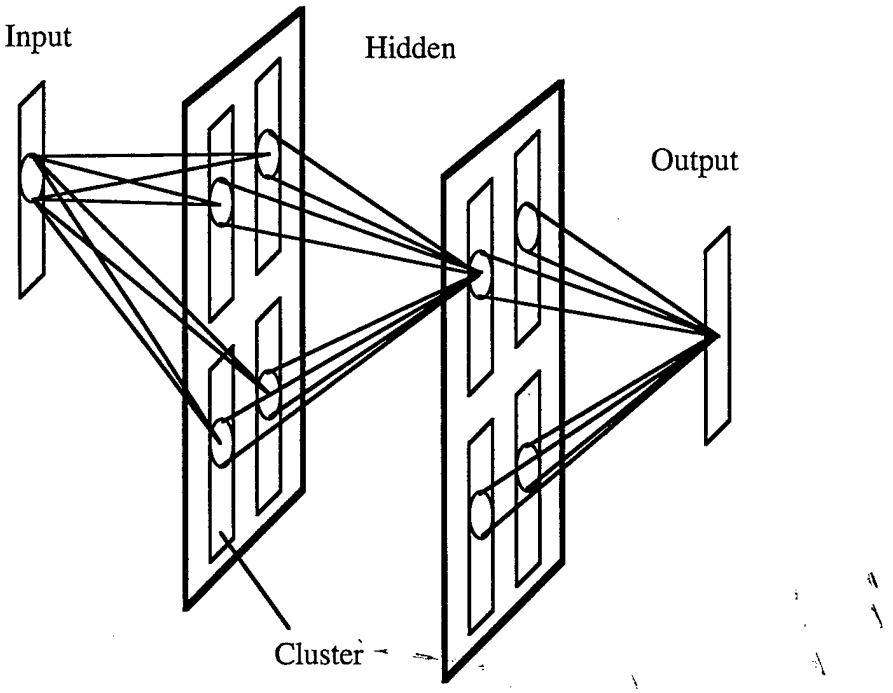

Figure 2. One-dimensional shift-invariant convolution neural network model.

every cluster of the lower layers. Each unit has a limited receptive field, and the interconnections between units are constrained to be locally shift-invariant.

The signal processing and the learning algorithm of the neural network are explained as follows. Let $N_p^l(x)$ and $O_p^l(x)$ represent the net input and the output, respectively, of the units (x) in the pth cluster of lth layer. Let the pattern of connectivity between the units in the pth cluster of the lth layer and the unit (x) in the qth cluster of $(l+1)$th layer be $W_{p,q}^l(x)$ where $l = (1,2,...,L)$, $p = (1,2,...,P^l)$, and $q = (1,2,...,P^{l+1})$. The input to units on the subsequent layers of the network is

$$N_q^{l+1} = \sum_{p=1}^{P^l} (O_p^l * W_{p,q}^l)(x) + b_q^{l+1}, \qquad (3)$$

where b_p^l represents the bias in pth cluster of the lth layer and the symbol $*$ denotes the convolution operation. The output of the units can be written as

$$O_q^{l+1} = f\left(N_q^{l+1}(x)\right), \qquad (4)$$

where $f(z)$ is a sigmoid function to denote the pointwise thresholding, written by

$$f(z) = \frac{2}{1+\exp(-z)} - 1. \qquad (5)$$

Let the tth change of the weight be $\Delta W_{p,q}^{l}(t)$ and the tth change of the bias be $\Delta b_{p}^{l}(t)$. The error function is defined as

$$E = \frac{1}{2}\sum_{i}\sum_{x}\left(T^{i}(x) - O_{1}^{L,i}(x)\right)^{2}, \qquad (6)$$

where $T^{i}(x)$ and $O_{1}^{L,1}(x)$ denote the components of the desired output profile and the actual output profile of the network for the training input profile i, respectively. At this time, the error back propagation algorithm in this model can be modified as follows:

$$\Delta W_{p,q}^{l}(t+1) = \eta\left(\delta_{q}^{l+1} * O_{p}^{l}\right)(x) + \alpha\Delta W_{p,q}^{l}(t), \qquad (7)$$

$$\Delta b_{p,q}^{l}(t+1) = \eta\sum_{i}\sum_{j}\delta_{p}^{l}(i,j) + \alpha\Delta b_{p}^{l}(t), \qquad (8)$$

$$\delta_{p}^{l} = f'\left(N_{p}^{l}(x)\right)\sum_{q}\left[\left(\delta_{q}^{l+1} * \tilde{W}_{p,q}^{l}\right)(x)\right], \qquad (9)$$

$$\tilde{W}_{p,q}^{l}(x) = W_{p,q}^{l}(-x), \qquad 10)$$

and, in the case of the last layer,

$$\delta_{1}^{L} = f'\left(N_{1}^{L}(x)\right)\left(T - O_{1}^{L}\right)(x), \qquad (11)$$

where $f'(z)$, η, α, and $T(x)$ denote the derivation of $f(z)$, the learning rate, the constant factor of the momentum term, and the desired output profile, respectively. Total two convolution neural networks are used to process each direction profile.

2.4. Binarization and filtering

The output profiles are the gray scale profile with 8 bit. Each profile is binarized with the center value , i.e. 128, of 8 bit gray scale. Since the output values depend on the probability of the input pattern in the training data set, it is reasonable to select 50% probability as the threshold. After binarization the labeling process is applied for limiting the number of the candidate edge to four. Although the number of the edge can be one or more than four for one profile, we restricted the number of the edge to within four, because the following overlapping process of two direction edge images compensates this variation. Two of the longest edge candidates are preserved through the labeling process.

For each direction, the binary edge image is reconstructed from its labeled profiles. The OR operation is applied between the horizontal and vertical binary edge image for overlapping each other. The morphological erosion filter followed by labeling is applied to the OR operated image to get the lung contour image.

3.0 Results and Discussion

The neural network used in this experiment had four layers. The input layers consisted of 256 and 310 neurons for the horizontal and vertical direction neural network, respectively. The output layers consisted of 232 and 286 neurons for the horizontal and vertical direction neural network, respectively. The hidden layers for the horizontal direction neural network consisted of five 252 neuron clusters and three 242 neuron clusters for the first and second hidden layers, respectively. The hidden layers for the vertical direction neural network consisted of five 306 neuron clusters and three 296 neuron clusters for the first and second hidden layers, respectively. Each neuron on the hidden layers and the output layer has a bipolar sigmoid function defined as

$$f(z) = \frac{2}{1+\exp(-z)} - 1, \tag{12}$$

and each neuron on the input layer has the following transfer function:

$$O_1^1(x) = \frac{2 \times I(x)}{\max\{I(x)\}} - 1, \tag{13}$$

where $I(x)$ denotes the pixel value of (x) in the input profile and $\max\{I(x)\}$ means the maximum pixel value in the whole profile.

In this training procedure, all weights started from random values between -0.1 and 0.1. The learning rate η and the momentum term α were 0.1 and 0.9, respectively. The training set for neural network learning consisted of 14 chest radiographs and their hand-drawn target images. The example images of both original and target image are shown in Figures 3 and 4, respectively. In this training set, one pixel on the target image corresponds to one training example, thus, the total number of training examples were $241 \times 310 \times 14$ and $296 \times 256 \times 14$ for the horizontal and vertical direction neural network, respectively. Since the numbers of free parameters of the neural networks were 234 , the requirement of VC dimension was satisfied [10].

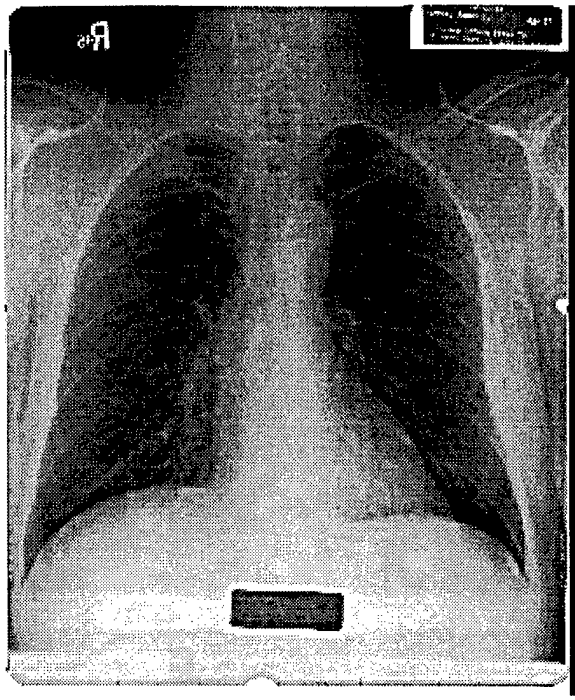

Figure 3. The original image for training.

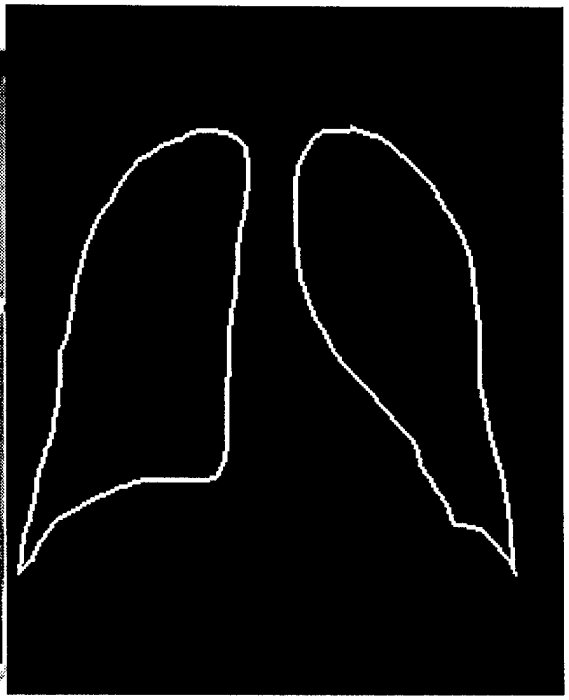

Figure 4. The target image for training.

After 40,000 training iterations, the neural network was used for the lung contour detection. Seventy-one sets of target, original, and output profiles on a vertical line of a chest radiograph are shown in Figure 5 (a), (b), and (c), respectively. An original image and its output binary contour image by using binarization, labeling and morphological filter are shown in Figures 6 and 7, respectively. The shift-invariant convolution neural network and the proposed postprocessing can detect the lung contour at 82% accuracy on average against test images following the same rules as for the training images in Figure 8.

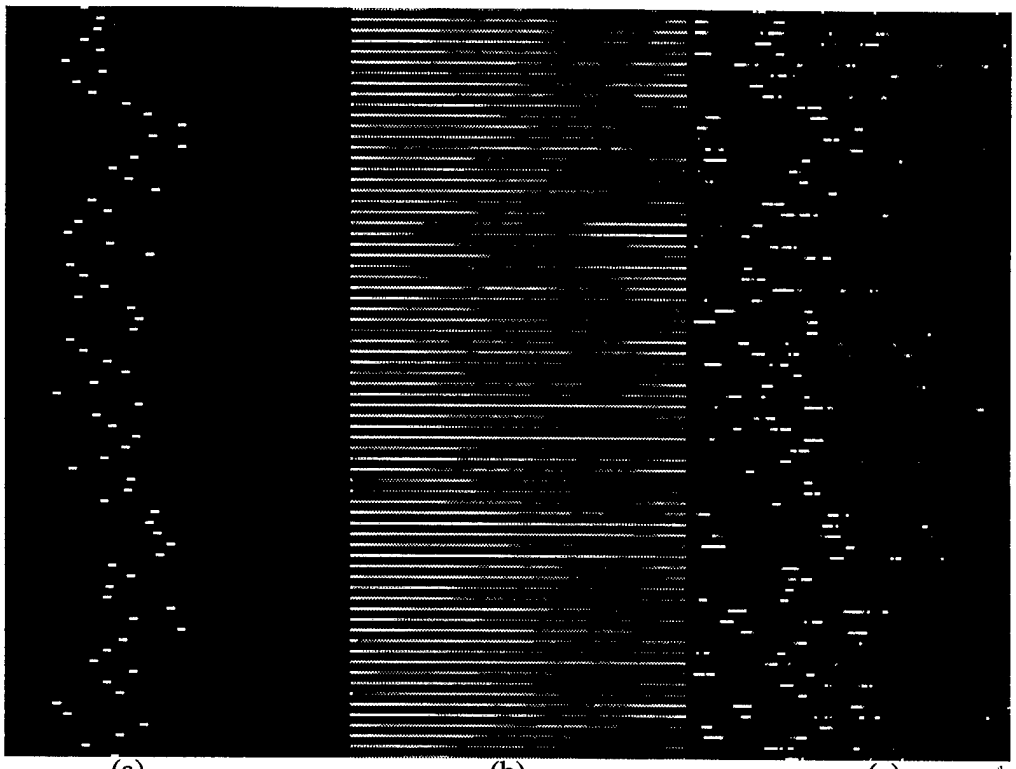

Figure 5. Seventy-one sets of (a) target profile, (b) original profile, and (c) output profile for the neural network.

4.0 Conclusions

In this report, we have described the use of parallel distributed convolution neural networks to detect the lung contour on digital chest radiographs. It was demonstrated that by training the neural network with 14 images, the neural network could be generalized for the processing of the remaining chest radiographs. In addition, the novel postprocessing followed by the process of the neural network provided the successful detection of the lung contour.

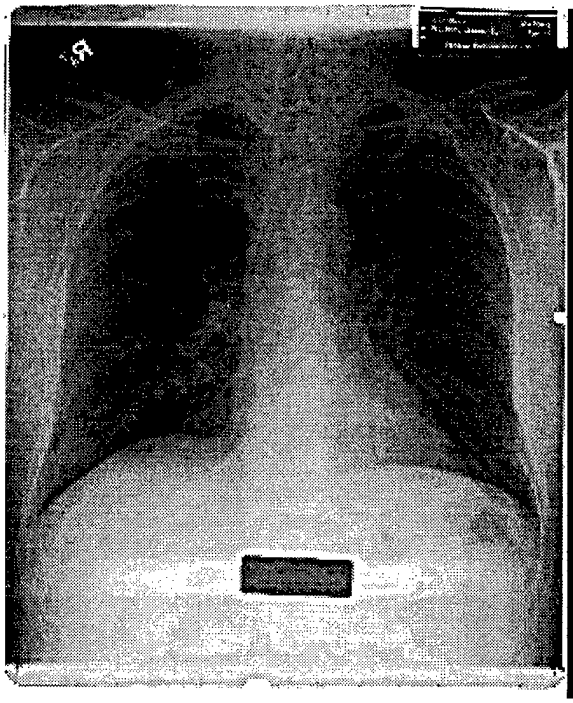

Figure 6. The original image for testing.

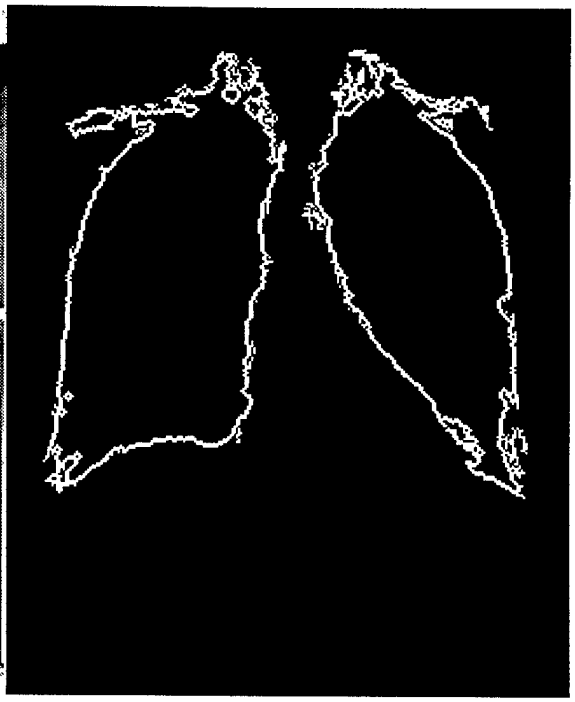

Figure 7. The output image of testing.

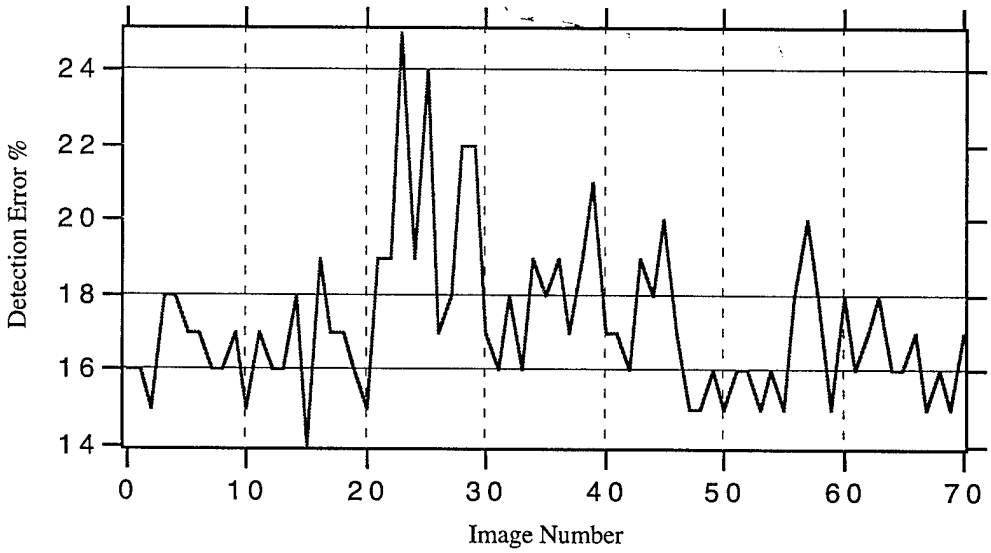

Figure 8. The lung detection error against 71 images at testing.

5.0 References

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2.3 Establishment of Data Base for CADx of Lung Nodules

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ABSTRACT

A properly acquired digital image data set is valuable information for research in digital imaging, image processing and computer aided diagnosis. The digitization of X-ray chest radiographs is to enable the evaluation of the performance of Georgetown Computer Aided Diagnosis (CADx) for detection of lung nodules on a large proven lung cancer database. This is a joint project between ISIS division of Georgetown University Medical Center (GUMC) and Johns Hopkins University. A data set of 700 cases containing more than 3000 films from the Johns Hopkins Archive were collected at ISIS center. These films are originated from the Johns Hopkins Lung Project (JHLP) co-directed by Dr. Stitik in 1970's. It constitutes a very large set of proven cases, some of which had lung cancer, some of which had lesions simulating lung cancer, and most importantly, many of which are known to be true negatives (i.e. no lung cancer). Because CADx increases false positives detection, some of which represent real, but non-cancerous nodules, being certain of true negatives is important. The objective is to test the Georgetown CADx algorithm in detecting lung nodules on chest radiographs and hence to improve the CADx detection system. This image set will be made available to other researchers in the future.

1.0 Introduction

Lung Cancer is one of the most common and deadly diseases in the world. The prognosis and the cure of lung cancer depend highly on the early detection and treatment of small localized tumors. The detection of lung tumors in the early stage of growth can result in a better prognosis for survival. The early detection and diagnosis of pulmonary nodules in chest radiographs are among the most challenging clinical tasks performed by radiologists. Previous studies showed that radiologists fail to diagnose small pulmonary nodules in as many as 30% of positive cases. A long-term lung cancer screening program, that was conducted at the Mayo Clinic found that 90% of peripheral lung cancers were visible in small sizes, retrospectively on earlier radiographs. Due to human observer errors, the current miss-rate in detecting small lung nodules larger than 3 mm in diameter is as high as 35% of the abnormal cases, of which on half of the missed nodules can be detected retrospectively. In the 5-year screening project at Johns Hopkins Hospital for early detection of lung nodules, it has been shown that the miss rate can be decreased to less than 20% if two or more radiologists work together. CADx has been shown to be a promising approach as a radiologist's assistant for improving diagnostic accuracy. It can serve effectively as a second reader of chest radiographs for the detection of lung nodules improving the accuracy of lung cancer detection as measured by receiver operating characteristic (ROC) analysis.

CADx of lung nodules was largely developed at the University of Chicago by people working under the direction of Kunio Doi. In 1991, Georgetown started its effort in CADx of lung nodules with the development of new algorithms. These algorithms were derived from techniques developed in Japan for recognizing numbers and letters and were substantially modified and first used in medicine by Georgetown. Georgetown currently

has four computer scientists working full time on various applications of CADx of lung and breast images using neural networks. A newly developed hybrid digital-neural CADx system is used to assist radiologists in early detection and diagnosis of lung nodules on digital chest radiographs. The fundamental approach of the research is to follow experienced radiologists' diagnostic procedure and incorporate their expertise into the computer program. The CADx system based on a double matching and two-level convolution neural network (CNN) architecture, is designed to achieve the performance of a high degree of "true-positive fraction" detection and low "false-positive fraction" detection. Essentially, the CADx performs two diagnostic functions:

1) location of suspected nodule areas (SNAs), also known as a "prescan process" on the digitized film image.

2) differentiation of "true" nodules from "false" nodules using a convolution neural network (CNN) architecture.

CNN is a two-level architecture which performs feature extraction and classification on raw images, rather than pre-identified subspace features. The first level CNN (CNN-I) aims at identification of nodules and nodule-like patterns. The second level CNN (CNN-II) aims at classification of "true" nodules and nodule-like "false" patterns. Fuzzy linguistic concepts and multi-label output encoding procedure were developed and applied for the 1st level neural training and interpretation of the activity distributions in the output neurons as normalized disease index (NDI). Tests of the algorithm have been done on Georgetown chest films and the Receiver Operating Characteristics (ROC) measurements show an area under the curve of 88 to 91%.

2.0 Preliminary Study

A preliminary study was performed by Dr. Lin at the ISIS center on 15 selected cases of JHLP X-ray chest radiographs. The goal was to ensure the quality of JHLP films still in good condition for digitization and CADx detection prior to large scale digitization.

A data set of 15 randomly selected cases containing 48 X-ray lung films were digitized at 175 micron by using a Lumisys laser scanner (Model: 150, Sunnyvale, CA). The image size was 2048 x 2560 x 12 bits. Each X-ray chest image was then preprocessed to 512 x 640 x 12 bits before being sent to the Georgetown neural-network based CADx for evaluation.

Results showed that the quality of 48 JHLP films is still in good condition for digitization and CADx evaluation. This indicates the reusability of the whole JHLP database for CADx study. In most cases, the CADx system correctly detected the cancerous nodules on the digitized films. In some cases, the CADx detected cancerous nodules at their early development stages when the radiologist missed the diagnosis. However, the CADx also missed the detection of some underexposed and large Pancoast tumors in some cases. The CADx system was designed to detect nodules with size 3 ~ 15 mm in diameter. The CNN classifier detected nodules with size slightly bigger than 15 mm, however, it failed in identifying nodules bigger than 20 mm in diameter. This indicates that the CADx system needs the improvement in detecting Pancoast tumors. It should be noted that the CNN training data was obtained from digitized Georgetown chest films using a Konica laser scanner (Model: KDFR, Tokyo, Japan) while the JHLP films were digitized by the Lumisys laser scanner. This indicates that the potential of the CADx system in the detection of lung nodules on digital images obtained from different X-ray machines and scanners.

3.0 Materials and Methods

The positive results of the preliminary study confirmed the feasibility of proceeding of large scale digitization on 700 cases JHLP X-ray radiographs. X-ray lung films were digitized at 175 micron resolution by using a Lumisys laser scanner (Model: 75, Sunnyvale, CA). Each case contains 1 to 5 films with the patient history up to 5 years. In total, more than 3000 films were digitized.

The configuration of the systems used for digitization is as follows:

a) LumiScan laser scanner (Model: 75). It is a PC based scanner which has the maximum resolution up to 2048 bits per line.
b) PC Pentium 150 MHz with 16 MB RAM and 1.2 GB hard disk. It is a networking computer which has the File Transfer Protocol (FTP) and Telenet capabilities.
c) SUN SPARC 20 workstation with an external 9 GB hard drive and 7 GB cartridge tape drive. FTP and telnet features are also available.
d) EXATAPE 8 mm data cartridge tape with 7 GB capacity.

Procedure:

Each X-ray chest film of size 14 in. x 17 in. was manually loaded into the feeder of the Lumisys scanner. Then, a scanfilm command was issued to the scanner from the PC in DOS mode. The scanning time for each film was about 2 min. Each digitized chest image was about 11 MB including the 2048 bytes header. When the number of digitized images reached the full capacity of the hard disk memory, the whole batch of images were then transferred to the external hard drive of the SUN workstation by using FTP. Prior to the storage in the 8 mm data cartridge tape, 10 % of the digitized images were randomly selected and visually inspected to ensure the quality of images digitized is satisfactory. If the visual inspection test is passed, each image was undergone a lossless compression to 6 MB size in order to save the storage space. All compressed images are finally downloaded into the data cartridge tape.

4.0 Results

Number of cases digitized: 700
Data size: 11 MB/image; 11 - 66 MB/case
Time for film scanning: 2 min./film
Time for ftp 1 GB image data from PC to workstation: 15-20 min.
Time for compression and download the images to 7 GB tape: 12 hrs./tape

All 700 cases containing more than 3000 JHLP X-ray chest radiographs were scanned, digitized, and stored in 9 data cartridge tapes.

5.0 Conclusion

A very large set of JHLP image database is created. In the next step, each digitized image will then be evaluated by the Georgetown CADx for lung nodules detection and then compared with the X-ray screening results. The performance will be measured by computing the area under ROC curves for sensitivity and specificity of CADx system. A protocol for digitization using PC-based film scanner to communicate to the UNIX platform is established. Though the tape storage has the merit of holding a large volume of

data, the data retrieval is very slow. Recently, a StorageTek WolfCreek storage system is installed at ISIS center. It is designed for central database using the StorageTek tape and software developed by Lockheed Martin in conjunction with Georgetown University. It has 1 terabytes of magnetic tape storage and two high speed magnetic tape drives. The special on-line staging feature of the system allows for fast data retrieval. In addition, the user interface developed by Lockheed Martin will allow users to access data through the Internet by using Netscape. After the whole system set-up is finished, all the digitized chest images will then be uploaded to the StorageTek system to provide the researchers a user friendly interface environment to store and retrieve all the images.

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2.4 The Impact of Standards in Teleradiology and Telemedicine

Primary Investigators

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ABSTRACT

The fundamental hypothesis that guides this research is that the implementation of standards is an essential condition for the creation of affordable seamless medical consultation. But the use of standards introduces overhead in the system performance. Radiological images are utilized for many Medical consultations and the increase in digitally acquired radiology images has led to the increased importance to focus on the use of DICOM and other standards for patient information exchange. The ISIS Center is involved in the creation of a Renal Dialysis Patient Management network to support renal dialysis patient management. This report highlights our research protocol in determining the impact of standards on the network.

1.0 Background

A Renal Dialysis Patient Management (RDPM) network connects remote dialysis clinics to a nephrologist at a tertiary care center to improve health care delivery and reduce cost. The nephrologist requires patient vital signs (e.g., temperature, arterial and venous pressure, blood flow), dialysis parameters (e.g., dialysate temperature, flow and conductivity) and access to the patient's clinical history including radiological images. While the real-time patient and dialysis data will be acquired from the participating clinics, the patient's clinical history is problematic. The complete record of a given patient may not necessarily be known to either the clinic or the tertiary care center. Therefore, it is necessary to accumulate this information from multiple institutions, as illustrated in Figure 1.

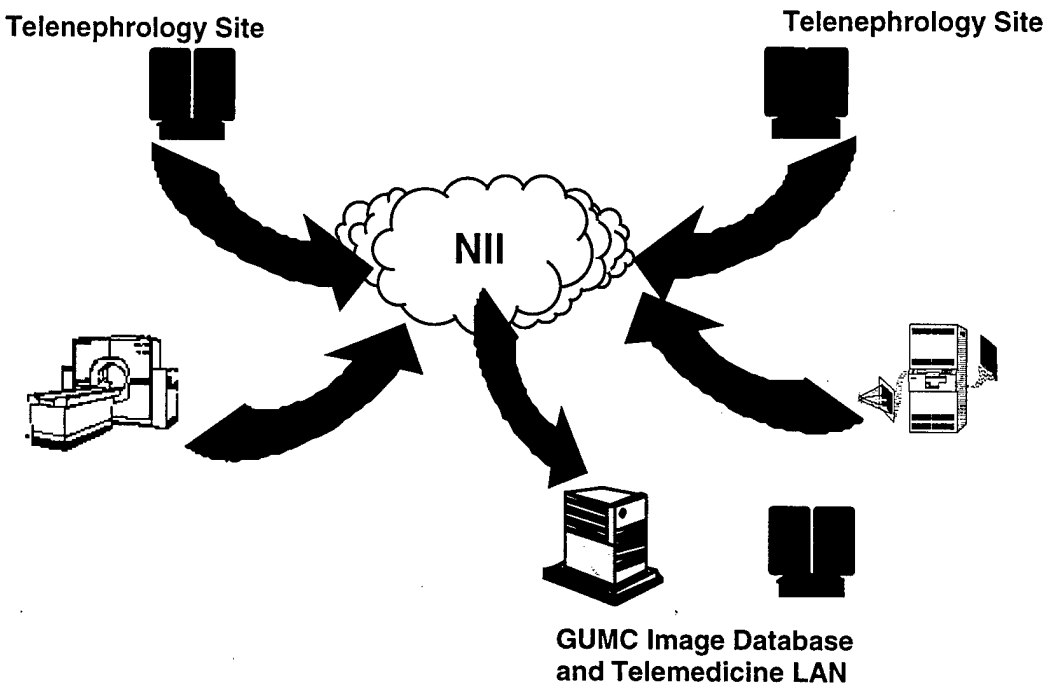

Figure 1. A patient's radiology images can come from anywhere.

The requirements of an RDPM network include a review of radiological images which increases the complexity of the telecommunications task. Standards based communication interfaces such as those provided by the Digital Imaging and Communications in Medicine (DICOM)[1,3] and Health Level 7 (HL7)[2] standards are essential. Our testbed will be the environment from which we perform evaluations of three important aspects of systems integration - connectivity, performance, and functional interoperability.

We have recently completed a 90 day project to design, test, and implement a global teleradiology network to support the US troops in Bosnia-Herzegovina. This compressed timeframe dictated our use of off the shelf hardware and software products, and our insistence on the use of standards by all vendors. While all the vendors in our project were DICOM compliant, approximately 1/3 of our time was spent resolving DICOM connectivity issues. This was a result of differences in interpretation of the DICOM standard by the different vendors, and errors in DICOM implementations. We felt that this percent of effort to implement a network based on standards was unacceptable.

The first step toward interoperability is to assure conformance to the standard. The DICOM standard requires a vendor to construct a conformance statement that clearly states (in a format specified in the standard) what subset of DICOM features and functions have been implemented. Of course, it is necessary to validate that the subject implementation actually matches the conformance statement. This conformance testing of DICOM implementations has been discussed by Meyer et. al [8]

By reviewing the conformance statements of all vendors involved in an implementation, one can come to a conclusion as to whether and to what extent interoperability is supported. Conformance statements and conformance testing alone, however, can not prove that two

systems can interconnect. A mechanism to test the interoperability of multi-vendor implementations is required.

Bradshaw and Prior[9] defined a basic Model of Communication (Figure 2.) which states that there are abstract objects or pieces of information that must be communicated between two communicating entities. In order for information to be communicated from one entity to another, the sending entity must represent the information as symbols and transmit the symbols to the receiving entity. The receiving entity must then interpret the received symbols back into information objects. There is communication when the two communicating entities view and utilize the information objects in the same ways.

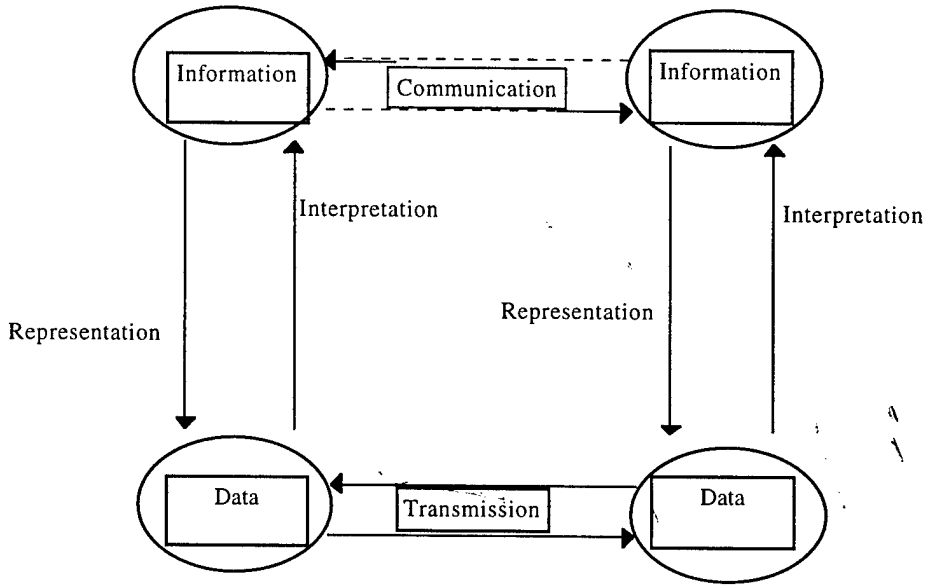

Figure 2. Model of communication.

DICOM connectivity precisely matches the general model of communication presented above. In the DICOM standard, information is contained in information objects. For both the sending and the receiving entities, the intent is that all of the information sent by the sending entity shall be received by the receiving entity and, because the semantic content of the transferred information objects is unambiguously defined, both entities should interpret the information in the same ways.

Bradshaw and Prior[9], through an initiative sponsored by the MEDPACS Section of NEMA, have defined the Guidelines for Cross-Vendor DICOM testing. To be precise, these guidelines support testing of DICOM interconnectivity. The objective is to provide a set of guidelines that vendors and other DICOM implementors can use in a consistent fashion to assure that their DICOM applications will interconnect and to provide users with a consistent view of DICOM product interconnectivity coverage.

Connectivity is an essential but not sufficient condition to guarantee a viable digital imaging network. The performance of the network must be ensured so that the information travels across the network in a timely way. Telemedicine applications often operate on local networks which provide for sufficient bandwidth and transfer rate. However, as we recently saw in our Bosnian deployment project, telemedicine applications can also work over satellites and other network environments where delays greatly affect performance.

Performance of a digital imaging network is affected at the basic network and DICOM levels.

Basic network performance at the TCP level is dependent on the bandwidth of the network as well as the delay. The product of bandwidth*delay is the buffer space required by the sender and receiver to obtain maximum throughput on the specific TCP connection. When bandwidth*delay is large, this is known as a "long, fat pipe" or long, fat network (LFN). These types of networks are not handled efficiently using standard TCP.

Gohel has noted, "The TCP protocol provides flow control and reliable data delivery by maintaining buffers at both ends of a connection. These buffers, known as socket buffers, are used to store data that is in transmission to the peer in a connection (send socket buffer) or that has been received from the peer and is waiting to be read (receive socket buffer). The size of these buffers (TCP buffersize) affect network throughput."[18]

Extensions to the TCP standard have been defined as RFC 1323[14]. This extension allows for TCP buffersizes of greater than 64K. There have been many tests that have proven that this extension is invaluable for satellite transmission performance improvements over standard TCP.[10,11,12,13]

Application throughput is dependent on the performance of DICOM application services and TCP/IP lower layer services. Several parameters within DICOM implementations can affect throughput performance. These parameters include:

- PDU size
- Association establishment and release times
- Implementation specific I/O data rates.

Work done by S. Moore and F. Prior[15] has shown that the factor which has the most impact on DICOM memory to memory transfer rate is the protocol data unit (PDU) size. This is the size of the packets passed between the systems. There is also some overhead due to association establishment and release, but this value is thought to be minimal in most applications.[8] Some DICOM implementation specific parameters which will have an affect on transfer rate are the number of times data is buffered, efficiency of DICOM parsing algorithms, disk overhead, and processor speed.

The different network infrastructures we have available to us in our testbed include 10baseT and 100baseT ethernet, ATM, satellite, and Internet access. The performance specifications of each of these infrastructures differs greatly. An ATM LAN was established in the Section of Radiological Computing and Imaging Science at Penn State University. Experiments were done to estimate the effects of varying TCP socket sizes and DICOM PDUs over multiple communications infrastructures. Similar studies will be done using all the available communications networks available to us through our testbed. An example of the type of results we can generate are shown in figure 3. This study measured the effect on transfer rates when socket size and buffer message size (referred to as Msg size in the figure) were varied.

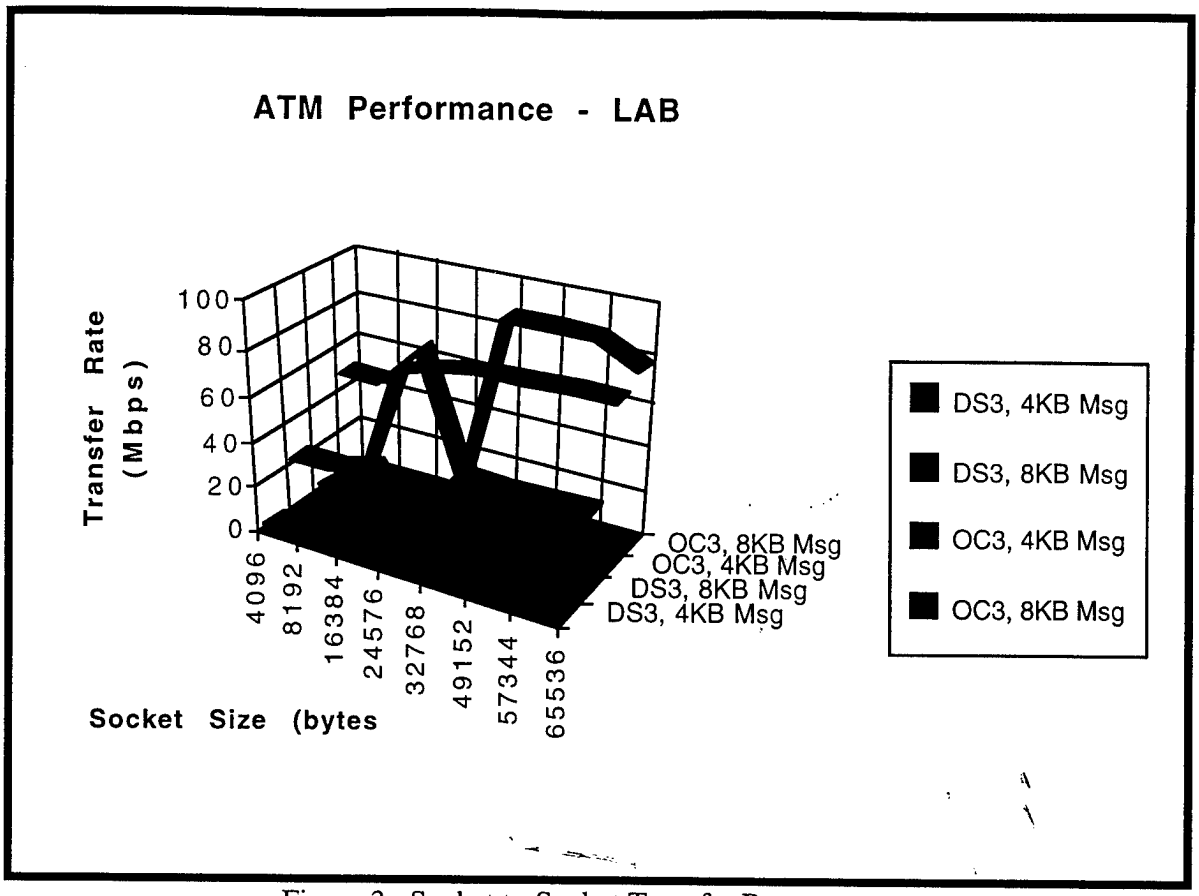

Figure 3. Socket to Socket Transfer Rates
TCP/IP-ATM: LAN and Simulated WAN

Connectivity and performance must exist for a network to be viable, however, the functional interoperability between devices on the network is equally important. The DICOM standard, while addressing issues of connectivity, does not really address interoperability. Hartmut Gnoyke and the committee for the Advancement of DICOM have created a document, still in draft form, that addresses extensions to the DICOM standard to specify categories of object attributes which are required for specific applications.[19] The applications that are the most important in an RDPM project include 2-D image display and worklist generation. While Gnoyke and the committee's work goes a long way towards defining the required attributes for many functions, more work is needed to ensure that for specific non-radiological projects, like RDPM, these extensions are sufficient for providing functional interoperability throughout a DICOM network.

2.0 Approach and Methods

As stated earlier, the nephrologist often requires the patient clinical history and radiological images when treating or reviewing a dialysis patient. The clinical history is often maintained within a computerized medical record at a specified institution. Most hospital information systems (HIS) utilize the Health Level 7 standard for communicating patient clinical data to other computerized systems. It needs to be determined whether the HL7 standard can support nephrology applications in its present state.

Connectivity and performance are the key parameters for evaluating a network. The integration of imaging devices is facilitated by the use of standards like DICOM. DICOM includes services that support image transfer, database query and image retrieval, hardcopy (film) printing, and image management functions. Implemented over TCP/IP transport, DICOM services provide multi-vendor connectivity.

Improvements in connectivity often come at the price of decreased performance. Advances in telecommunication services provide a wide array of possible infrastructure to support telemedicine applications. Maximizing performance across multiple network carriers while maintaining multi-vendor connectivity is vital. HL7 is defined as an application layer protocol which can run over TCP/IP. Therefore, an evaluation of TCP/IP performance is extensible to HL7 as well as DICOM.

For advanced telemedicine applications, connectivity is a necessary prerequisite but it is not sufficient. Enhanced clinical utility requires the exchange of information with unambiguous semantics. Images and other telemedicine information must be fully exploitable by the receiving system. Thus functional interoperability, the ability to exchange medical information which has clinical utility on both sides of a connection, is a key requirement. The DICOM standard addresses interconnectivity of networked devices but does not address functional interoperability. The necessary extensions to DICOM to provide demonstrable interoperability must be determined.

3.0 Nephrology Patient Record

The nephrology patient record maintains a lot of information that is kept by a computerized information system. Evaluation of the manual operations of a nephrology clinic and the review of the dialysis patient by the nephrologist will tell us the key pieces of data from a patient's clinical history required by the nephrologist to properly review and treat a patient. After an observation of the manual procedures, a review of the HL7 standard will be undertaken to determine whether the standard in its present form is sufficient for supporting applications like RDPM.

An observer will be placed in both the nephrology clinic where the patient is having dialysis as well as with the nephrologist to record the types and frequency of use of information used or required but unavailable while treating a patient. This information will then be collated and an extensive review of the existing HL7 standard will be done to match the data to existing elements in the standard. Extensions to the standard will be proposed if it is determined that the current HL7 implementation is not sufficient.

4.0 Connectivity

Connectivity is the ability of devices to communicate. DICOM connectivity addresses the ability of two DICOM application entities to establish a connection and to exchange DICOM messages in a manner consistent with the DICOM protocol[9]. That is, two devices whose software conforms to the requirements of the DICOM message exchange protocol, syntax, encoding rules, and information object definitions, can exchange messages.

In order to claim DICOM conformance, each vendor must provide a written conformance statement following the format of part 2 of the DICOM 3.0 standard.[1] This conformance statement must clearly state the subset of DICOM functionality provided by the vendor. The conformance statement specifies the service classes, information objects,

and communications protocols supported by the implementation.[16] The conformance statement will also describe the extensions, specializations, or privatizations of the standard supported by the implementation. Because these conformance statements are defined, a user that understands DICOM can determine whether and to what extent multi-vendor's DICOM implementations will communicate.

Only the equipment within our testbed that is related to the RDPM network will be evaluated for DICOM interconnectivity. Thus the multiple workstations available to us, plus the computed radiography device, film digitizers, and ultrasound archive will be part of our evaluation project. The pairs of vendors shown in Table 1 will be evaluated for DICOM connectivity and the identified service classes will be used for the measurement. To perform this evaluation, a CR study will be captured on the computed radiography DICOM gateway and used as the basis for communicating to all the workstations. The same plain films will be used for the film digitizer as well so that we ensure consistency in the studies and images that are being used for the evaluation.

Table 1. DICOM Interconnectivity Matrix

	CR	FD	US	MV	AR	VQ
CR				store_CR	store_CR	
FD				store_SC	store_SC	store_SC
US				store_SC	store_SC	store_SC
MV					store_CR store_SC	store_CR store_SC
AR				store_CR store_SC		store_CR store_SC
VQ				store_CT store_SC	store_CT store_SC	store_CT

Legend:

CR = Fuji AC-3
FD = Lumisys film digitizer
US = Agfa IMPAX ultrasound network
MV = Siemens MagicView
AR = GE Acquisition Review
VQ = Picker VoxelQ

To properly measure the connectivity amongst the vendors listed in Table 1, we will evaluate the DICOM conformance statements along with criteria in the Guidelines for Cross-Vendor DICOM Testing and evaluate and score each vendor. Summary reports will be generated using both the conformance statements and the results of the cross-vendor testing. These statements will be used to validate that an implementation behaves in accordance with its associated conformance statement with respect to the DICOM Standard.

The degree of interconnectivity based on the percentage of test cases a given pair of systems can pass will be measured. The test cases will be developed in compliance with the Guidelines. By looking at a broad cross section of systems (see Table 1) we will be able to assess the degree to which DICOM in its current form addresses the interconnectivity requirements of the market.

We will then analyze the summary reports for patterns of failure and compare the results to the DICOM standard to determine gaps in the standard versus implementation or interpretation problems by vendors.

5.0 Performance

The goal of this evaluation is to survey a broad spectrum of vendors and modalities and evaluate them for DICOM conformance not to determine specific implementation weaknesses, but to survey the general state of DICOM connectivity

As stated before, connectivity alone is not sufficient for creating a clinically useful RDPM network. Therefore we will evaluate the causal relationship between changes at the TCP and the DICOM levels to understand where increases in performance can be obtained and where bottlenecks exist. This will be done by evaluating standard TCP/IP performance in our testbed to obtain a baseline. Then we will evaluate the impact on performance of implementing RFC 1323 to increase the TCP transmit and receive windows. This will attempt to increase performance at the basic network level of connectivity. We will also evaluate the DICOM performance of the multiple vendors in our testbed and make assessments of their implementations and its effect on performance. We will do this by looking at varying the PDU size, and measuring implementations for association connect times and times until responses. This will be done for different types of studies. Most of our evaluations of the DICOM performance will be measured using the DICOM store service classes.

Utilizing our existing multi-vendor testbed, we will apply modifications to the basic network communications levels (TCP layer) to determine the increased performance which can be expected in the local area network (LAN) and wide area network (WAN). The suite of LAN/WAN environments that will be evaluated include Ethernet - 10baseT and 100baseT, and ATM for LANs, ATM, and satellite links for WANs.

TCP performance problems arise when TCP packets are sent over large pipes with long delays. Using the information in RFC 1323, we will evaluate our testbed for performance improvements do to LFNs.[14] Our teleradiology network installed in Germany, Hungary, and Bosnia is an ideal example of a LFN since we see satellite delays of up to 1000 ms. There has been some work done to evaluate the use of RFC 1323 (an extension to the TCP standard) to increase the TCP send and receive windows when using satellites for image transfer.

Basic networking parameters can have a tremendous effect on throughput performance, depending on the network environment. The parameters which will be evaluated for TCP performance over various network environments are:

- Socket size (TCP window size)
- IOsize (Buffer size)

We will measure the socket to socket transfer rates as a function of TCP buffersize and IOsize. DICOM performance is most directly determined by a combination of TCP/IP performance and DICOM PDU size.

6.0 Experimental Design

A 2^3 factorial design with two replicates (Table 2) will be utilized to explore the main and interaction effects of the three parameters: Socket Size, IOsize and DICOM PDU size on DICOM transfer rate for each of the 5 network types described above. The runs in each replicate will be randomized. Response surface methodology (Box, Hunter, and Hunter) will be used to define the minimum number of additional experiments needed to fit a polynomial response surface and determine the parameter values that yield the optimum transfer rate.

Table 2. Initial Design, No RFC Enhancement

Run	Socket Size (KB)	IO size (KB)	PDU Size (KB)
1	4	4	4
2	64	4	4
3	4	64	4
4	64	64	4
5	4	4	128
6	64	4	128
7	4	64	128
8	64	64	128

Based on preliminary data from ATM LAN/WAN configurations it is assumed that the maximum of the response surface will fall at the maximum socket size. To explore the impact of RFC 1323 enhancements, particularly increased socket size, the design will be repeated for each network with the addition of RFC 1323 enhancements. In this second phase design, the socket size parameter will initially vary from a minimum of 128KB to a maximum of 1 MB. Table 3 illustrates this second design. Response surfaces will be fit to this new data and compared with those from the original configuration.

Table 3. Initial Design, RFC Enhancement

Run	Socket Size (KB)	IO size (KB)	PDU Size (KB)
1	128	4	4
2	1024	4	4
3	128	64	4
4	1024	64	4
5	128	4	128
6	1024	4	128
7	128	64	128
8	1024	64	128

DICOM transfer rate is also dependent on implementation dependent factors. As a final experiment the basic transfer rate of a C-Store operation will be measured for the following SCU/SCP pairs (Table 4) using 2 common network infrastructures (10baseT ethernet and satellite communications) and the vendor's standard TCP/IP and PDU size settings:

Table 4. SCU/SCP Pairs

SCU \ SCP	MV	AR	VQ
CR	x		
FD	x	x	x
US	x		
MV	x	x	x
AR	x		x
VQ	x	x	x

Testing will be done over 10baseT to get a baseline for performance in industry and compare it to the optimization surface found in the previous experiments. The DICOM implementation will be compared to the performance characteristics seen with factorial design. Then we will look at the results in another domain, specifically satellite communications.

7.0 Methods

To determine TCP socket to socket performance we will use Netperf. Netperf is a performance benchmarking tool designed to measure bulk data transfer rates over a variety of network infrastructures. Using TCP and the Berkeley sockets interface, Netperf permits both user and TCP buffer sizes (socket size) to be varied.[17] We will first take time measurements based on default socket and IOsize.

We will implement the Sun Consultants TCPLFN and re-evaluate our testbed for improved performance. Thus enhancements in performance due to TCP parameter changes will be measured using Netperf. Besides looking at pure transfer speeds, the percentage of retries due to lost packets will be evaluated too. All this data will be collected and used to make a determination of the optimal performance possible utilizing the different network environments.

Multiple socket sizes will be used, starting with the smallest and largest available when using the TCPLFN patch.

Next we will need to evaluate our testbed for DICOM performance. We will do this using a network sniffer tool and measuring portions of the DICOM message transfers. We will examine the patterns of packet transmissions with the sniffer. To evaluate DICOM performance, we will measure the time between an association request and the association acceptance, the time between the start of a STORE request and the STORE response (this will vary greatly depending on the size of the images and the number of images in the study), and the association release and release response times. These values will be measured for all DICOM transfers in our network as shown in Table 4.

Each combination of acquisition devices and workstations will be examined for the default PDU size, and the times associated with association establishment and release, and store request and response times. The same image data will be used for each of the tests. A CR study will be captured on the CR gateway and used to send to the 3 different workstations. Then, that study will be used to test communications between the workstations. The times associated with the association establishment and release will be noted, as well as with the start and completion of the store request and response. We will note the PDU size used for the communication.

To test performance changes over satellite, we will utilize the existing network in Bosnia to send CR images from Bosnia to Germany. We will then simulate this environment using a satellite delay simulator and 2 routers to connect the CR equipment to a MagicView workstation. We will simulate the actual test to ensure that the simulation environment matches the real network in the field. The other connections can be simulated using the satellite delay simulator.

8.0 Functional Interoperability

The DICOM standard as currently written assures multi-vendor connectivity. The next great challenge facing the medical imaging community is true interoperability, or "plug and play" performance. Assessment of interoperability is a complex task as any pair of communicating devices may have widely differing functionality and "correct" utilization of exchanged data is dependent on the clinical context. So, for example, the inability of a workstation to correctly determine the real world pixel size of a received CT image may not lead to a significant functional deficiency in a standard body imaging context but would be a problem in an orthopedic context where accurate measurements are critical.

A straightforward approach to assessment of functional interoperability utilizes the following algorithm:

- enumerate the functional repertoire of the receiving device,
- identify one or more clinical contexts in which the device is used,
- identify a criterion for judging correct operation of each function in each context,
- devise a test suite that validates each function using test data sets provided by the communicating device.

While easily articulated, this algorithm is difficult to generalize since there is no standard for either the suite of functions a device should support or how those functions should operate. There is an approach, however, suggested by the work of Gnoyke[19], that can potentially lead to standardization. By looking at a set of similar products from multiple vendors (e.g. the set of medical imaging workstations designed to support primary radiology diagnosis) one can identify suites of common functions needed to support basic capabilities. For example, the most common function suite in medical imaging is that needed to support basic display capability for 2-D image sets. The goal of this analysis is to identify the basic set of functions that are common to all implementations supporting the target capability, taking into account a range of reasonable clinical contexts. Once the function suite is identified, a more detailed analysis can be undertaken to determine its basis of support, i.e., the set of input parameters required. This requires not only the identification of parameter names but the determination of precise semantics for each parameter.

The identification of capabilities, their supporting function suites, and underlying parameter sets is a difficult but important research task. Armed with this information, it is possible to cross correlate with DICOM Information Object Definitions and identify:

- missing parameters
- incorrect or inadequate semantics
- incorrect typing (in the DICOM context typing denotes whether an attribute is mandatory, optional or mandatory but null values are permitted).

The standard can then be appropriately amended or extended to identify the supported capabilities and articulate the basis of their support.

9.0 Experimental Design and Methods

Our approach to evaluating and determining the parameters for functional interoperability as an extension of the DICOM standard will be based on our multi-vendor network. Two experiments are proposed:

- Assess the degree of functional interoperability of two existing DICOM implementations,
- Determine the basis of support for two selected clinical capabilities.

To explore the methodological issues involved in functional interoperability assessment the Siemens MagicView workstation and the Fuji CR (as they currently exist on our testbed) will be assessed using the following algorithm:

- Enumerate the functional repertoire of the MagicView based on user manuals and operational experience.
- Using the clinical contexts of primary radiologic diagnosis of GI/GU cases and clinical review of GI/GU cases for RDPM, identify correctness criteria for each function.
- Based on the above analysis a test suite will be developed that validates each function using appropriate test data sets provided by the Fuji CR.
- Execute the test suite and analyze the results, highlighting points of failure.
- Refine the interoperability testing algorithm based on the experience gained during the test.

The results of this experiment will provide a basis of understanding of the process of interoperability testing, the limitations thereof, and a preliminary estimate of the degree of interoperability mismatch between two representative DICOM implementations.

For the second experiment two capabilities have been identified for study:

- Image Display: Determine the basic display attributes required for clinically useful two- dimensional image display for primary radiologic diagnosis of plane film (CR, LFD) cases.

- Worklist Generation: Determine the parameters necessary to generate worklists (based on DICOM query/retrieve service class) to support clinical review of radiologic examinations. (Note: a worklist is defined in supplement 10 of the DICOM standard as: "the structure to present information related to a particular set of tasks. It specifies particular details for each task. The information may support the selection of the task to be performed first and may support the performance of that task.")

A separate analysis will be undertaken for each capability.

All workstations available on our test bed (vendors: Siemens, General Electric, Picker) will be studied using the following methodology:

- The functional repertoire of each workstation will be enumerated and the suite of common functions included in the Image Display capability identified.
- Each function in the suite will be analyzed by inspection of the user interface, review of user manuals and vendor supplied design documentation, and parameter variation experiments (i.e., vary key parameters of injected DICOM information objects and observe the effect), to determine the set of required input parameters.
- The relevant DICOM information object definitions will be analyzed to determine necessary modifications.
- A report will be generated summarizing the results and proposing changes to the DICOM standard. This report will be presented to the DICOM Base Standards Working Group (WG VI).

The results of this experiment will be presented at a DICOM implementor's workshop (periodically held at NEMA headquarters under the auspices of the Committee for the Advancement of DICOM).

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2.5 Computed Radiography System Support at MDIS Sites

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ABSTRACT

Computed radiography (CR) systems are an integral component of MDIS as the general radiography acquisition device. Since these systems by themselves are considered a new modality for the technologist, radiologist, and physicist, proper operation and care of the CR readers ensures high quality image acquisition into MDIS. We have, over several years of research and clinical use of CR systems, achieved an in-depth understanding of the functions and operations of multiple CR systems as single devices and as components of larger systems. Often the members of ISIS staff are requested by the military to provide on-site technical support on the us of CR.

1.0 Introduction

The purpose of periodic short visits to DoD sites utilizing MDIS is to assist MATMO personnel with acceptance testing and to spend some coaching time with the technologists. The technologist training, after initial applications by the vendor, has proven to be a superb manner in which to update the civilian staff and to coach the very transitional enlisted personnel. Formal presentations are conducted for technologists when time and staffing allow. Information is supplied to supervisors about the CR Training Course offered by Georgetown and arrangements are currently under way to conduct the course at different MDIS user sites to capture a larger audience and utilize the expertise of the other instructors.

Each site visit includes an inventory and inspection of the equipment and the manner in which the final interpretation of the image occurs either by hard copy, soft copy or a combination of both. An inventory of the parameters within the readers is conducted to ensure high quality hard copy output and adjustments are made when appropriate using Madigan and Georgetown settings as a guideline. Acceptance testing of the CR component is performed according to the QA/QC protocol developed at Georgetown and according to the protocol developed by MATMO.

The following reports supply a thorough review of each site visited by Dot Artz from January 1996 to August 1996.

2.0 Fort Gordon, Augusta GA--Dwight D. Eisenhower Army Medical Center January 1996

Purpose: Per MATMO personnel, the operation of the AC-1+ unit being used at DDEAMC is not optimal and questions exist whether the interface to the MDIS system is what it should be compared to other MDIS sites. I plan on conducting hands-on technologist training for the AC-1+ and provide coaching for all shifts. Through observation and testing, verify and identify interface problems and if they can be solved, actively participate in ensuring quality images. I plan on performing some stepwedge tests to confirm that the EDR setting of FIXED found on the ET does in fact work and if successful will train the technologists how and when to use it and what benefit it provides

for difficult and/or tightly or off-collimated exams. Through communications with Maj. Williamson, the following exams are difficult to obtain quality images: some PA chests, port. chests, x-table c-spines, and shoot-through lat. hips.

Thursday January 18, 1996 (8:30AM-10PM):

Met with SSG Leingang and LTC Ralston to better determine where the primary problems exist and what I could do in my short visit to correct them. Per Col. Ralston, the lat. c-spines are the biggest problem images along with an occasional portable chest and portable abdomen exams. I indicated I would be able to change some algorithms to improve image quality from the AC-1+ and would create a specific menu item for the c-spine swimmers view. I also met with the Loral site employee, Dave Dozier. Dave's expertise lies more in hardware than software and right now the problems are software issues. Dave is going to be replaced with someone else in March who has a better software background. Dave called Chicago to check on adding new organ codes. Apparently it should not be difficult to add new codes into the MDIS database.

Initial observations:

1. A significant number of exams that can be ordered through the CHCS ordering system do not exist in the MDIS system. Most of the exams in CHCS do, however, exist within the AC-1+ reader.

2. The MDIS organ codes match the Fuji MPM codes exactly. This makes menu item changes easier within Fuji.

3. None of the CR cassettes are lead-backed. This has been proven to cause significant problems with scattered radiation thus image degradation

4. The CR equipment in place is the Siemens Digiscan and is currently under acceptance testing along with the entire MDIS system.

5. The techs. were trained on the CR unit in August although the reader was not operating until a few weeks ago. Some limited additional training has occurred with only a few technologists.

6. Until recently the techs. were not changing organ codes to match the actual exam being performed. The techs. just recently started to use a grid routinely with the CR for normally gridded exams screen/film.

7. Experimenting with the different EDR modes has to this point not been very successful for the FIXED mode. The evening crew has discovered the SEMI mode works very well for tightly collimated exams.

8. The majority of CR exams I saw today were of high quality.

9. Soft copy images problems: Mediastinum area in chests too light

   Two images on the same patient were superimposed when called up for viewing.

   Radiologists do not prefer soft reading but have been instructed to dictate from the soft copy.

10. Improving the hard copy images will benefit the other departments within the medical center where soft copy viewing is not available yet.

11. Major image transmission problems from Fort McPherson to DDEAMC. Patient information was transmitted but the images either never made it across and the images that did were full of artifacts and completely undiagnostic. Possible cause was attributed to break in the T1 line.

Activity List:

1. Listened to problems the technologists have been experiencing and in most cases could offer immediate solutions. See next.

2. Provided coaching for day shift most of the morning. Due to short staffing, a formal meeting to go over CR "tips" was not possible.

3. Attended QA meeting with Col. Ralston and other supervisory staff. Gave them a brief impression of my morning and offered formal training to be provided by ISIS staff in the near future.

4. SSG. Leingang and I conducted some stepwedge tests and phantom tests to determine how the SEMI and FIXED mode affected the image. The SEMI mode works the same as it would in a Fuji exclusive system. The FIXED mode allows the operator to choose a number ranging from 0.0 to 5.0 by tenths. Since these numbers do not correspond to the FIXED mode in the reader of 100, 200, 300, etc., we needed to determine what the relationship was to the speed fixed to the image using the MDIS system. The findings are as follows: **FIXED 2.00 = a fixed speed or S# of 400**
   FIXED 1.50 = a fixed speed or S# of 1265
   FIXED 4.00 = a fixed speed or S# of 4
   FIXED 1.00 = a fixed speed or S# of 4000

We concluded that the higher the number chosen at the ET of the MDIS system, the lower the actual assigned S# is through the CR unit. Apparently, Loral simply inverses the numbers in their system to the response of the CR. They used a certain logarithm that results in the odd range of actual S#s. Subsequent phantom images we obtained to confirm the results from the stepwedge exposures. We shot a mimic swimmers view using the lat pelvis phantom as a close likeness to the thickness of a patient's shoulders, using 85 kVp 80 mAs at 40" FFD, and ran it using FIXED 2.00. Beautiful image! We asked the evening crew to try it on any c-spine cases. We will review these on Friday AM.

The FIXED mode can be used to overcome difficult exams such as the lat. c-spine, ribs, axillary shoulders, lat hips, and any other exam where large image density differences occur due to anatomy. The SEMI and FIXED modes can also be used where tight collimation is desired (SEMI) or where the anatomy cannot be centered to the center of the imaging plate (FIXED). These two EDR settings provide the technologist with a means of controlling what the reader does for them instead of the reader controlling how they do exams! This is a significant accomplishment for other MDIS users and will be forwarded to other users and to Loral and Siemens. Congrats DDEAMC!

Friday Jan. 19, 1996 (6AM-4:30PM):

Activity List:

1. Reviewed the settings within the CR unit and changed parameters to match Madigan/Georgetown settings. I also enabled the "flip" and "rotation" on the most common exams used at DDEAMC.

2. Prepared and presented out brief document for LTC Ralston

3. Coached technologists not on duty Thursday.

4. Checked hard copy image quality after parameter changes. The changes made a marked improvement on the general abdomen exam and on extremity exams.

5. Checked in with the evening crew to answer any questions.

6. Provided SSG Leingang with addresses and phone numbers and written documentation.

PARAMETER CHANGES:

None of the EDR modes would change to SEMI

HEAD:

Paranasal Sinus:	Rotation and flip activated
Mandible:	**GA** 1.0 to 0.9

CHEST:

Chest General:	Rotation and flip activated **RN** 4 to 5

ABD.:

Abdomen General:	**GA** 1.1 to 0.9 **RN** 3 to 8 **RE** 1.5 to 1.0 Rotation and flip activated

PELVIS:

Lumbar Spine:	**GA** 1.1 to 0.9 **RN** 5 to 7

UPPER EXTREMITY:

Humerus/Elbow:	Rotation and flip activated **RN** 5 to 7
Forearm/Wrist:	Rotation and flip activated **RN** 5 to 7 **GT** O to N
Hand:	Rotation and flip activated **RN** 5 to 7 **GT** O to N
Finger:	Rotation and flip activated **RN** 5 to 7 **GT** O to N

LOWER EXTREMITY:

Knee/Femur:	Rotation and flip activated
Tib/Fib/Ankle:	Rotation and flip activated **RN** 5 to 7 **GT** O to N
Foot:	Rotation and flip activated **RN** 5 to 7 **GT** O to N
Toe:	Rotation and flip activated **RN** 5 to 7 **GT** O to N

Sat. Jan. 20, 1996 (8:30AM-) :

Spent all morning and early afternoon at the Med. Center. Since the morning was slow, I was able to go over much of the CR system with the weekend crew. I outbriefed SSG Leingang and spoke to LTC Ralston about the soft copy reading and image transmission problems. Overall he was very appreciative of my short visit and approved the parameter changes I made in the AC_1+.

3.0 Wright-Patterson Medical Center, Dayton Ohio 3-11-96 and 3-12-96

Purpose: Evaluate operation of the CR component of the MDIS, provide instruction to the technologists where necessary, and offer suggestions for improved operation and utilization of the CR system. This evaluation is in an effort to move to soft copy reading at Wright Patterson Medical Center.

Overall impression: Operations appear to be running very smoothly with excellent quality assurance by the assigned technologists. All techs., even those in training, appear to operate all aspects of MDIS from image acquisition at the CR component to the verification process very well. The in-house physicist Susan and the Q/A technologist Walene (sp?) have a clear effort in place for new employee orientation along with on-going training for technologists. Currently hard copy images are being interpreted by the radiologists.

A great deal of interaction occurs between the Q/A tech., and the tech. who performs the examination. When a problem image comes across, the Q/A tech. reviews organ code, S#, image orientation, anatomy and pathology.
Problem images could be reduced in number with more coaching by the Q/A tech. prior to exposure, i.e. cassette orientation, correct organ code, EDR selection, exposure factors for HR vs. ST imaging plates.

I showed a number of the technologists including the QA technologists how to use the EDR setting of FIXED at the exam terminal. Subsequent phantom testing was planned with the personnel from Madigan.

I spoke briefly with the physicist and provided her with a packet of handouts from our CR Training Course.

The confidence of the technologists using the system is high. The techs. feel the CR reader (FCR 7000) is too slow for their work load (over 100 exams per day shift).

CR equipment evaluation: WPMC uses a mixture of ST-IIIN, ST-V, and HR-IIIN plates. The ST-V plates are from a fairly recent shipment (IP number start with 051) and most of them are showing signs of wear. Some plate cracks are appearing within the anatomy area of the plate and not along the edges.

The cassettes are all lead-backed, but in most of the cassettes, the lead is bubbling which will eventually peel and possibly fall into the reader causing mechanical down time and/or image artifacts.

The cassettes containing a HR plate have been differentiated from the others with colored edge around the cassette.

Every image from the FCR 7000 that handles the routine work had a dust artifact from the light guide. This seemed to be easily overlooked by the radiologists and was brought to engineering's attention. The light guide was cleaned when the work flow slowed down.

The shutter to both readers is routinely kept open so I suggested that by closing the shutter after a cassette is removed the dust artifacts would decrease and the preview image also paints approximately 5 seconds faster.

I alerted appropriate personnel to my equipment observations.

4.0 WALTER REED ARMY MEDICAL CENTER (WRAMC) April 10 & 11, 1996

Request for visit: Maj. Morgan Williamson, MATMO

Purpose: Provide coaching and instruction to the technologists working in the orthopedic area at Walter Reed on the CR equipment. Evaluate image quality and system operation between the Fuji CR equipment and the 3M dry printer. Discuss potential image improvements with the charge technologist (Tony Swails) and the radiologist (Dr. Shapiro) who heads musculoskeletal imaging.

Impression:

Equipment:

1. Fuji components: The AC-3, IDT, HIC 654 workstation, and the magnetic card reader/writer all functioned properly.

2. 3M 8700 dry printer: Appeared to function properly. D-max set to 3.0 with clear and blue-based film.

Image Acquisition:

1. The technologists' use of the CR system for image acquisition is excellent.

2. Technique and positioning requirements for a CR system are being utilized and the coaching provided by Tony is very good.

3. I provided the techs. with the following information:

A. The imaging plates are bright light sensitive so in the event an exposed plate needs to be removed from the cassette, the plate should be removed in low level room light to prevent erasure of the image. If partial erasure of an image does occur due to bright light exposure, the resultant S# runs high. The reader perceives an under exposure.

B. After heavy use, the clips that keep the cassette closed may become weak and pop open when a cassette is handle, possibly dropping the plate onto the floor. This rarely occurs, but the techs. needed to be careful when handling the cassettes.

C. Thorough explanation and some trial of the SEMI, FIXED, and SEMI-X modes was covered with the techs. These different EDR (exposure data recognizer) settings give the techs. an additional tool to create the optimum image particularly for exams that involve large density differences like ribs, axillary shoulders, x-table hips and lateral cervical spines. The variety of EDR settings are a great tool also when the area of interest cannot be placed in the center of the plate due to limited patient mobility.

D. Reviewed the slight changes in use of kVp and mAs for CR vs. screen/film. Kvp has less effect on contrast with CR than with screen/film so using a higher kVp will not produce a flatter image but will ensure that the anatomy is adequately penetrated and information reaches the plate. If the technique needs to be increased, increase the kVp before adjusting the mAs. If the technique needs to be decreased, lower the mAs before adjusting the kVp. Using too much kVp can result in a dark image similar to screen/film because the incredibly short wavelength of the beam penetrated the anatomy and the plate, depositing little exposure on the plate.

E. Centering, collimation, and lead shielding within the image all play a key role in the resultant image quality and S#.

F. The center cell should be used for all photo timed examinations including PA chests.

Image Quality Analysis:

1. The hard copy quality from the 8700 is good on the 10 X 12 and 8 X 10 images. 14 X 17 images have some noise artifact due to the image interpolation from Fuji to 3M.

2. Changing the image processing parameters in the Fuji component can result in better image quality; however, the affect of the changes on the image appear different between the workstation monitor and the hard copy.

3. Improved visualization of the soft tissues on bone work was accomplished by changing the GT factor from O to N. Usually when one of the parameters is changed the GA (contrast) and the GS (density) must be changed slightly to achieve an acceptable image on the monitor and on film.

4. To overcome some of the inherent noise seen on the 14 X 17 images, we experimented with decreasing the RE (frequency enhancement) factor to create a smoother image. When the RE is decreased there is a reduction in the perceptibility of the noise, but trabecular detail is also compromised. The amount of acceptable loss is dependent on the radiologists' preference.

5. The S# is a useful tool for trouble-shooting "extreme" images. If an image appears very light, very dark, or very noisy, the S# can be used to determine over or under exposure to the plate. If the S# falls within the normal range and the image quality is very poor, there may be a hardware or software problem in the Fuji reader or the 3M printer. Explore all options and take careful note of plate size, centering of part to center of plate, collimation, orthopedic appliances, patient size, etc.

Summary

The equipment at WRAMC being used in the orthopedic area is operating according to the specified system configuration. The technologists have a solid understanding of CR imaging and are operating the equipment correctly. The images generated by the dry printer are of diagnostic quality; however, some improvements may, over time, be accomplished through ongoing feedback between the technologists and radiologists and ultimately to Fuji and 3M. Both companies involved, in my experience, work to continually improve their products and utilize clinical feedback from their users toward a positive outcome.

The images overall do look "different" than typical screen/film images. The Fuji/3M imaging system can be equated to a new screen/film system. The "different" appearance is not necessarily bad, but compromises are made in resolution when viewing CR images. The power of the system lies in it's ability to reprocess images lighter or darker, magnify an anatomical region, and reprocess for specific pathology enhancement all from a single exposure. The technologist and radiologist expertise are in place to work through difficult exams.

A slight increase in technique is not unusual for larger anatomical regions because although the screen/film system is, for example, a 400 speed system , the variations in chemistry, temperature, and general maintenance of the film processor, may drive the speed of the system up to around 600-800. The CR reader speed is 200-400. Because this is computer-based, the amount of "play" with technique is very limited.

I provided Tony with some material from the CR Training Course at Georgetown and also left some applications along with my card.

5.0 OSAN AIR FORCE BASE, OSAN KOREA 6-10-96 through 6-14-96

Purpose: Conduct acceptance testing on the AC-1+ component of the MDIS system and provide technologist training.

AC-1+ testing:

1. Sensitometry of the film processor--ok

2. Sensitivity check at 80kvp
50ma
1.25mas
80" SID
IP size: 10 x 12, STIIIN

Results: For 5 exposures, 2 had a S# of 200, 1 S# of 220, and 2 with a S# of 236. The optical density readings over the center of four quadrants of the hard copy were just above the MDIS requirement for acceptance testing(1.10-1.30). Shading correction performed on the AC-1+ should easily correct the problem. The flat field images showed no gross artifact, although very faint vertical light stripes were seen. As the light guide within the reader ages, these artifacts will become more conspicuous. The plates are 3 years old and some evidence of phosphor cracking was apparent on the flat field exposures. Ideally these plates should be pulled from service as most of the cracks are within the area of the plate that would be covered by anatomy.

Successive flat field and test pattern exposures produced results within specs.

No image jitters or gross nonuniformity

AC-1+/Lockheed exam terminal (et) interface:

1. The MPM codes within the CR reader are identical to the organ code within the Lockheed system. Improvement could be made between the interpretation of the order entered into paris and the organ code attached to that particular order. For example: when a paranasal sinus series is entered into paris, the organ code attached matches skull general. Unless the technologist changes the organ code at the exam terminal, the image plates are processed with the skull algorithm producing a suboptimal study due to the differences in collimation and exposure for the separate exams.

2. The ability to choose a specific EDR (exposure data recognizer) setting works well. I explained how to use the different settings most effectively for difficult exams or exams where large density differences occur naturally. The fixed mode when set to 2.00 produces an image with a S# of 400. This mode turns the corrective nature of the reader off. If the tech. Uses a good kVp and mAs for a 400 speed screen/film system and chooses fixed 2.00, the reader is essentially turned into a glorified film processor. The resultant image quality for a difficult exam is improved with a greater ability to window and level through the large density differences.

CR image processing parameters:

Since personnel at Osan leave after only one year, the need to have ready access to the hard copy x-ray results in a hard copy being printed for some studies. The hard copy, in some

instances, is also being used for primary interpretation when soft copy detail is not satisfactory.

The parameters within the CR reader are a copy from Madigan so the orthopedic exams have been changed to achieve a satisfactory screen/film appearance.

The following parameters have been changed to produce a better hard copy image at Osan from the ac-1+ processor:

Lumbar spine higher RN and lower RE to reduce noise and increase bony detail
Abdomen general changed re from 6.0 to 0.5 to reduce noise enhancement
Foot changed RN from 4 to 7 to increase trab. detail

As more exams are performed CR, the parameters may need to be changed to produce a screen/film likeness if hard copy continues to be used from the AC-1+ processor.

Image artifacts:

Two types of image artifacts are occurring on a regular basis:

1. Corduroy artifact: this artifact appears on the hard and soft copy and looks like dark widewale corduroy.

   Cause: non-reciprocating grid grid lines running parallel to the main scan direction of the reader. Example: cross-wise chest in upright wall bucky.

   Solution: Do all cross-wise chests in room two with the upright reciprocating grid. Position patient length-wise for a PA chest as often as possible.

2. Phosphor plate cracks: This artifact appears as very fine white lines running along the long axis of the phosphor plate.

   Cause: physical damage due to age.

   Solution: replace plates. Most of the 10 x 12 plates are showing cracking and discoloration which affects image quality.

Overall impression and recommendations:

1. Ac-1+ operation is within expectation assuming the shading correction has been recalibrated.

2. All of the cassettes except the 18 x 24 should be lead backed to reduce scatter and improve image quality.

3. The overall condition of the STIIIN plates is bordering on unsatisfactory due to the cracking and discoloration. Not all need to be replaced, but the worst ones should be as soon as possible. The HRIIIN plates are fine.

The care of the plates is ok. They are primary and secondary erased on a regular basis. Some improvement could be made on cleaning the plates every 30 days.

Because image quality improves by using the smallest plate possible for the anatomy being radiographed, STIIIN 8 x 10 plates are needed at this site. They presently have none.

4. The condition of the cassettes is very good. They are being stored correctly and rotated daily. No evidence of loose hinges, cracked bar-code windows, or broken frames.

5. The technologists confidence with the CR device is improving as they use the equipment more often. After reviewing the options available at the et to improve results, I noticed an increase in confidence level within 2-3 days and an improvement in image quality.

6. Hard copy image quality: The actual print format from the AC-1+ processor is to spec. Some parameters were changed to improve the hard copy quality. The images that are printed from the Kodak printer are less than adequate since no Fuji parameters are interpreted through to Kodak. Unless more than one image is printed per 14 x 17 film, the image is expanded to fill the film. These images lack contrast detail due to the lack of post-processing. When two or more images are printed on the film, they are minified.

7. Soft copy image quality: Meets the expectations of the technological capabilities of the system. In some clinical cases the lack of sharpness and edge enhancement lead to misdiagnosis or a miss altogether by the radiologist that probably would not occur with hard copy interpretation. Any type of contrast enhanced processing with edge enhancement would be of great benefit.

8. QA/QC: Daily, weekly, monthly, semiannual, and annual QA/QC protocols need to be put into place and conscientiously performed by the technologists and the vendor. Since this sight is considered a little more remote than most, reports on the procedures performed should be generated on a regular basis and reviewed by the vendor and MATMO. I cannot stress enough the importance of a very detailed maintenance log. A log helps track problems with the equipment and with the users making troubleshooting the system easier and more efficient.

In general the system at Osan moves images produced through the AC-1+ as it should. The monitors need to be checked and calibrated on a weekly basis to ensure proper soft viewing. Since the system has been in place for a few years the nuts and bolts problems should have been worked through. The remaining serious issue with this and other systems is the soft copy image quality.

Another issue revolves around the users taking ownership of the system. Each site has specific and different demands on their system and by working closely with the vendor engineers at their site, problems should be solved quicker and more effectively.

6.0 Walter Reed Army Medical Center
9-05-96

Purpose: Address the persistent image quality problems with 14 X 17 acquired images from the AC-3 through the Imation (3M) 2210 out to the Imation (3M) 8700 dry printer. Consistent problems remain particularly with the lumbar spine and pelvis examinations where the images appear to have too much digital noise and the orthopedic surgeons prefer a 100% image size for pre-operative prosthetic hip replacement images.

Discussion: Four concurrent actions were discussed to resolve the above issues.

1) Ensure room calibrations and automatic settings are accurate and are set for a 200-400 speed system which matches the CR system speed. Along with room calibrations, make sure the technologists are receiving proper training and coaching to use the system (GUMC CR Training Course).

2) Since the problem seems to lie in the interface between the AC-3 and the 8700, investigate other interface options out of the CR system. Calls and inquiries to HUP and Mayo Jacksonville were recommended since both sites are happy with the image quality off of their CR out to the 8700.

3) Bill Betten of Imation will be asked to provide a time frame on the new software release for the 2210 that reduces noise on the interpolated 14 X 17 images and will also produce a true 100% size from the 14 X 17 acquisition.

4) Objective image evaluation of lumbar spine examinations by the radiologists covering the orthopedic area will occur for a one month period of time starting on October 1, 1996 and end November 1, 1996. A form will accompany each image where the technologists records technical factors, patient size in centimeters, source-image distance, use of the phototimer, and the S#. On the same sheet, the radiologist will evaluate centering, collimation, and overall image quality from a scale. The radiologists, at the end of the month, will again evaluate each image along with Mark Murphy, MD and Dot Artz, RTRM. The results will be used for discussions with the vendors and for internal quality improvement.

Akamai Annual Report

Chapter 3

Advanced Topics in Visualization

3.1 Multispectral Modeling and Visualization of Localized Prostate Cancer

Primary Investigators

Jason Xuan, MS
Joseph Wang, PhD

ABSTRACT

The digital imaging network can be a powerful and effective infrastructure to support advanced visualization. Study of these new visualization techniques will provide important information for the design of data base for digital imaging network. To understand the database requirement the following study was undertaken. The reconstruction and visualization of the localized cancer will for the first time create a statistically significant master model to more accurately define tumor volume and distribution, pathways of the needle biopsies, and extent of tumor beyond the margins, thus allowing improved understanding of prostate cancer behavior and current diagnosis-staging methodology. To achieve this goal, we propose to reconstruct and visualize previous imaged surgical prostate specimens permitting interactive 3-D mapping of the entire prostate specimens into a spectrum of distribution, multicentricity, and volume, thus allowing a comprehensive analysis of pathological information with a statistically significant master model of the prostate cancer. The originality and innovative nature of the engineering involved rely on: (1) an elastic model is developed to perform nonlinear contour interpolation; (2) a symmetry-seeking deformable model is proposed to reconstruct the surface of objects; and (3) a finite mixture distribution is formulated to create a statistical master model for the pattern of localized prostate cancers.

1.0 Introduction

1.1 Research Goals and Specific Aims

Adenocarcinoma of the prostate (ACP) is the most prevalent male malignancy and the second leading cause of death by cancer in American men. Detection of prostate cancer has been dramatically increased through improved screening programs including digital rectal examination (DRE) and plasma prostate-specific antigen (PSA) radioimmanoassary. When either the PSA or DRE is abnormal, transrectal ultrasound (TRUS) is performed for needle biopsy guidance. If a lesion is detected, TRUS is utilized to conduct tissue characterization and/or guide selective needle biopsies. A standardized US six quadrant core-needle biopsy is performed if no lesion is detected by TRUS. After biopsy-proven diagnosis of prostate cancer, preoperative endorectal magnetic resonance imaging (EMRI), incorporated with all previous procedures, may be performed to evaluate the prostate gland, helping determine the best treatment plan (surgery, radiation therapy, and/or hormonal therapy). The outcome in the individual case depends on the size, distribution, localization, stage, and grade of the tumor. Due to highly variable behavior of the prostate cancer, treatment has been hampered by problems inherent in the conventional diagnosis and staging methodology, leading to a serious dilemma: **treatment is still too late in some patients, while others are perhaps being treated unnecessarily**. As many as 50% of radical prostatectomies are either unnecessary (because the cancer is too small) or ineffective (because the cancer has

already spread beyond the prostate capsule). This represents an **enormous cost** to an already overburdened health care system. Evidence indicates that many prostate cancers are undetected by TRUS because of unsatisfactory accuracy (sensitivity and specificity), and although the only way to confirm a diagnosis of the prostate cancer is by a biopsy of six tiny samples from different parts of the prostate, one out of five cancers will be missed by biopsy. Furthermore, no current imaging modality is able to depict the entire prostate capsule at a 7-50 μm resolution, which is required by the staging system to rule out subtle capsule penetration by ACP. A major limitation of conventional biopsy and staging, though to be, at least in part, responsible for these deficiencies, is the lack of a practical method to spatially and selectively guide specific points in the biopsy technique. The complex disease pattern, distribution, volume, and multicentricity exhibited by prostate cancer during its development are therefore not accurately accounted for by current biopsy strategies or correlated to the findings with EMRI staging. *In the absence of such a method, a major unresolved question is to know whether selective biopsy is fundamentally limited because of intrinsic random distribution of the prostate cancer or whether better strategy can be developed if a multispectral master model of the prostate cancer is created.*

We propose to address this issue with a unique and novel method based on the modeling and visualization of the localized prostate cancer using previous imaged surgical specimens. This method permits interactive 3-D mapping of the entire prostate with 150 to 200 surgical specimens subdivided into a spectrum of distribution, multicentricity, and volume, thus allowing a comprehensive analysis of pathological information with a statistically significant master model of the prostate cancer. The **general goal** of this project is to determine whether this method can provide a better strategy for optimizing and guiding selective biopsy for a higher rate of prostate cancer detection and the best possible representation of tumor grade and extension. The **main hypotheses** to be tested are that multispectral modeling and visualization of the localized prostate cancer reconstructed from surgical specimens can (1) create a distribution, and multicentricity of the prostate carcinoma, (2) simulate biopsies and correlate the findings with the grade and volume of the tumor in the whole operative specimen to determine the accuracy and pitfalls of current biopsy-image based staging system, and (3) help to develop new selective strategies leading to an increased rate of cancer detection and an improved accuracy of tumor diagnosis and staging.

1.2 Clinical Significance and Engineering Research Design

The reconstruction and visualization of localized cancer will for the first time create a statistically significant master model to more accurately define tumor volume and distribution, pathways of the needle biopsies, and extent of tumor beyond the margins, thus allowing improved understanding of prostate cancer behavior and current diagnosis-staging methodology. By correlating the findings in the simulated biopsies with the whole prostatectomy specimen, it is possible to optimize biopsy strategy to give the best possible representation of tumor grade and extension. The accuracy of diagnosis and staging will be increased, leading to improved treatment planning and subsequently a decreased health care cost. In addition, identification of pre-oppressively critical anatomical structures (e.g. external urinary sphincter and neuromuscular bundles), using the master model and interactive visualization, may reduce the known risks of post-operative incontinence and impotence. **The technical objectives** of this project are: (1) reconstruct the prostate gland and localized cancers from surgical specimens using the state-of-the-art graphical modeling, (2) create a statistically significant multispectral master model of localized prostate cancers by fusing 150-200 clinically-proven cases, (3) develop an interactive 3-D visualization tool with advanced display techniques, (4) simulate multiple core needle biopsy in an augmented reality, and (5) quantitatively analyze and correlate findings of

biopsy-image based staging systems. In the next two sections, we will present our approaches on reconstructing the prostate model and creating the statistical master model of localized prostate cancer.

2.0 Surface Reconstructions and Visualization of the Surgical Prostate Model

The purpose of this project to reconstruct and visualize previously imaged prostate specimens to define tumor volume and distribution, and pathways of needle biopsies, thus allowing improved understanding of prostate cancer behavior and current diagnosis-staging methodology. The Method of this step can be summarized as follows: Data acquisition and registration are performed on clinically-proven surgical specimens digitized by a Leafscan 45 Scanner at a resolution of 1500 dpi. After a feature-based manual registration, contours are extracted manually by pathologists using Photoshop on 10-14 slices with 4 μm sections at 2.5 mm intervals for each case. **Contour interpolation** is aimed to increasing the sample rate in the stacking direction in order to reconstruct sufficiently accurate surfaces of the prostate and its internal anatomical structures. Instead of using linear interpolation, we develop a 3-D elastic contour model to compute a 3-D force field between adjacent slices thus enabling a "pulling and pushing" metaphor to move the starting contour gradually to the final contour. **Surface reconstruction** consists of two steps: in the first step, triangulated patches are tiled between adjacent contours with a criterion of minimizing the surface area; in the second step, those triangulated patches are refined by using a deformable surface-spine model. A deformable spine (axis) of the prostate model is determined from its contours, then all the triangulated patches are contracted to the spine through expansion/compression forces radiating from the spine while the spine itself is also confined to the surfaces. The surface refinement is governed by a second-order partial differential equation from Lagrangian mechanics, and the refining process is accomplished when the energy of this dynamic deformable surface-spine model reaches its minimum. **Interactive visualization** will be achieved by using the state-of-the-art 3-D graphics toolkit -- *OpenInventor* featuring triangulated meshes, NURBs, light sources of different types, draggers and manipulators for direct 3-D interaction. The **innovative work** of this research consists of : (1) we develop a 3-D elastic interpolation method which computes a 3-D force field to smoothly move the starting contour to the final contour for yielding a reliable and meaningful interpolation result; (2) A deformable surface-spine model is proposed to dynamically refine the triangulated patches for improving the accuracy of the prostate surface model.

3.0 Statistical Modeling and Visualization of Localized Prostate Cancer

The **purpose** of this step is to develop a statistically significant master model of localized prostate cancer with pathologically-proven surgical specimens to spatially and selectively guide specific points in the biopsy technique for a higher rate of prostate cancer detection and the best possible representation of tumor grade and extension. The **Method** can be summarized as follows: Based on 150 - 200 surgical specimens of prostates, we have developed a surface reconstruction technique to interactively visualize the clinically significant objects of interest such as the prostate capsule, urethra, seminal vesicles, ejaculatory ducts and the different carcinomas, for each of these cases. In order to investigate the complex disease pattern, i.e., the distribution, volume, and multicentricity exhibited by prostate cancer during its development, we created a statistically significant master model of localized prostate cancer by fusing these reconstructed computer models from all cases, followed by a quantitative formulation of the 3-D finite mixture distribution.

Based on the reconstructed prostate capsule and internal structures, we have developed a multi-feature based registration technique to automatically align all surgical specimens together through optimal translation, rotation and scaling. By labeling the voxels of localized prostate cancer by "1" and the voxels of other internal structures by "0", we can generate a 3-D binary image of the prostate that is simply a mutually exclusive random sampling of the underlying distribution of cancer occurrence. Then we added all the images of those specimens and normalize the results to obtain a 3-D histogram of localized prostate cancer characteristics. In order to quantify the key parameters such as distribution, multicentricity, and volume, we used a finite generalized Gaussian mixture to model the histogram, and estimate the parameter values through information theoretic criteria and a probabilistic self-organizing map. Utilizing minimally-immersive and stereoscopic interactive visualization, we developed an augmented reality to allow the physician to virtually hold the master model in one hand and use the dominant hand to probe data values and perform a simulated needle biopsy. An adaptive self-organizing vector quantization method is developed to determine the optimal locations of selective biopsies where maximum likelihood of cancer detection and the best possible representation of tumor grade and extension can be achieved theoretically.

We have successfully reconstructed the prostate gland and localized cancer from surgical specimens using proposed graphical modeling, and create a statistically significant master model of localized prostate cancer. This method permits interactive 3-D mapping of the entire prostate with 150 to 200 surgical specimens subdivided into a spectrum of distribution, multicentricity, and volume, thus allowing a comprehensive analysis of pathological information. The preliminary results show that a statistical pattern of localized prostate cancer exists, and a better understanding of disease patterns associated with tumor volume, distribution, and multicentricity of prostate carcinoma can be obtained from the computerized master model. The **innovative work** of this step consists of : (1) To the best of our knowledge, this work has created the first 3-D statistical model of localized prostate cancer that can be used to investigate the disease patterns of prostate cancer behavior and characteristics; (2) A minimally-immersive and stereoscopic interactive visualization technique is developed that permits accurate simulation of different biopsy protocols; (3) Based on this computerized statistical master model, for the first time it becomes possible to develop new selective biopsy strategies leading to an increased rate of cancer detection and an improved accuracy of tumor diagnosis and staging.

4.0 Conclusions

The proposed surface reconstruction and visualization technique has been applied to several prostate specimens which demonstrates its promising use in modeling tumor volume and distribution, in planning the pathways of needle biopsies, and in reducing the known risks of post-operative incontinence and impotence. Furthermore, we have developed a statistical modeling and visualization of localized prostate cancer reconstructed from surgical specimens, that help to better understand prostate cancer patterns, to correlate the findings with the grade and volume of the tumor to determine the accuracy and pitfalls of current biopsy-image based staging system, and to guide a new selective biopsy technique.

3.2 3-D Spine Imaging and Image-Guided Minimally Invasive Spine Surgery

Primary Investigators

Joseph Wang, PhD
Jason Xuan, MS

ABSTRACT

Visualization of medical images depends on acquisition of high quality images, image processing and a data base for the images. Chronic back pain is a major cause of long term disability in the United States and throughout the world. Analysis of these patient to determine whether or not they would benefit from surgery remains less than optimal in predicting which patients will benefit and which will not benefit from surgery. Management of the patient with continuing or recurrent back pain following surgery is difficult and following surgery, it is even more difficult to determine which patients may benefit or fail to benefit from subsequent surgery. Three dimensional imaging holds the potential to provide better answers to these several problems. During the initial stage of this project, we have investigated the suitable 3-D imaging modalities that can provide the information required by our specific aims and selected MRI and CT as two major modes. Based on these images of the spine structures, the information from these two modalities will be fused together through a site model based image registration and mutual exclusive component merging. Enhanced by computer graphics based visualization tools, including both surface and volume rendering, the physicians will be able to manipulate the 3-D data of the true spine structures for each patient and make an optimal treatment plan, practice in a virtual environment, and ultimately perform image-guided minimally invasive spine surgery.

1. Introduction

Research Goals and Specific Aims

Chronic back pain is a major cause of long term disability in the United States and throughout the world. Analysis of these patients to determine whether or not they would benefit from surgery remains less than optimal in predicting which patients will benefit and which will not benefit from surgery. Management of the patient with continuing or recurrent back pain following surgery is difficult and following surgery, it is even more difficult to determine which patients may benefit or fail to benefit from subsequent surgery. Three dimensional imaging holds the potential to provide better answers to these several problems. Based on continuous or overlapping cross-sectional image data sets obtained using MR, CT or Spiral CT and potentially with fusion of images from MR and CT and perhaps nuclear bone images, additional information could be provided that would assist in the evaluation of these patients.

The goal of this 3-D visualization process is to allow the radiologist and surgeon to look into the neuroforamina in greater detail than is now possible by rotating a 3D dataset so that the neuroforamina can be "visually" traced along its entire length looking for areas

of narrowing within it. This will require rapid (real time) rotation with precise control and the ability to "fly into" the neuroforamina for visualization.

A secondary goal is to evaluate the degree of fusion following surgery by the creation of 3D snakes that can look through adjacent complex interdigitating surfaces to determine if there is any curved surface that can pass between any portion of the fusion bony tissues.

The final clinical importance of this cannot be predicted because these techniques have not been effectively applied before to this problem and therefore we cannot be certain that what we find will be of value, but prospectively, one would expect that it will be.

2. Clinical Significance and Engineering Research Design

There are two general types of causes of back pain: nerve impingement and mechanical derangements. Nerve impingement results from some structure pressing on the spinal nerve. Common causes are intervertebral body disk herniation, osteophytes from degenerative arthritis and degenerative disk disease, fibrosis often associated with these first two causes and combinations of these three causes. Often the neuroforamina is narrowed by these processes. Mechanical derangements are a more diverse group and include degenerative arthritic type changes, disk degeneration without disk herniation, fibrosis, ligamentous hypertrophy and combinations. In the post operative patient, failure of surgical fusion is an additional cause.

The purpose of this project is to reconstruct and visualize multimodality imaged spine structures to define the cause of the pain, and the spatial relationship among those components involved in the spine motion, thus allowing improved understanding of spine dynamical behavior and current diagnosis-treatment methodology.

The method of this step can be summarized as follows:

- **Data acquisition** are performed on both MRI and x-ray CT modalities with two modes: one is a sequence of 2-D images, one is a directly reconstructed 3-D volume data. After a feature-based manual registration, quantitative features are extracted automatically and the fine registration is performed by a site model based image registration technique.
- **Component segmentation** is aimed to extract hard structures from CT images and soft tissues from MR images in order to reconstruct sufficiently accurate surfaces of the spine and its internal joint-nerve structures. In our previous research, we develop intensive expertise in medical image segmentation in the applications of MRI-PET brain image fusion. We will use both statistical model-based image segmentation and joint edge detection and region growing segmentation techniques.
- **Surface reconstruction** consists of two steps: in the first step, triangulated patches are tiled between adjacent contours with a criterion of minimizing the surface area; in the second step, those triangulated patches are refined by using a deformable surface-spine model. A deformable spine (axis) of the spine structure is determined from its contours, then all the triangulated patches are contracted to the spine through expansion/compression forces radiating from the spine while the spine itself is also confined to the surfaces. The surface refinement is governed by a second-order partial differential equation from Lagrangian mechanics, and the refining process is accomplished when the energy of this dynamic deformable surface-spine model reaches its minimum.

- **Interactive visualization** will be achieved by using the state-of-the-art 3-D graphics toolkit -- *OpenInventor* featuring triangulated meshes, NURBs, light sources of different types, draggers and manipulators for direct 3-D interaction. Utilizing minimally-immersive and stereoscopic interactive visualization, we developed an augmented reality to allow the physician to virtually hold the master model in one hand and use the dominant hand to probe data values and perform a simulated microsurgery.

This method permits interactive 3-D mapping of the entire data volume of spine structure thus allowing a comprehensive analysis of multispectral information from different modalities. The **innovative work** of this step consists of : (1) To the best of our knowledge, this work has created the first 3-D model of multimodality spine structure that can be used to investigate the disease patterns of back pain behavior and characteristics; (2) A minimally-immersive and stereoscopic interactive visualization technique is developed that permits accurate simulation of different surgical protocols.

3.3 Color-Feature-Based Finger Tracking for Palpation Quantification

Primary Investigators

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ABSTRACT

The advanced application of virtual reality using multimedia data base will have a significant role in medicine in the near future. As a part of digital multimedia visualization research, we have initiated a project dealing with a tactile sensors. We are to build a system using vision-based motion tracking technology to gather quantitative data about the breast palpation process for analysis of breast self-examination (BSE) technique. By tracking the position of the fingers, the system is able to objectively quantify the procedure of the BSE process, thus can improve our knowledge on the effectiveness of this technique so as to optimize the search strategy and assure full coverage for breast cancer detection. By visually displaying all the touched position information to the patient as the BSE is being conducted, the system can provide an interactive feedback to the patient and create a prototype for a computer-based BSE training system. In this paper, we describe the vision-based finger tracking technique used in the system, which uses color information in feature extraction and can track 3D positions of the fingers in real time. Experimental results confirm the good performance and effectiveness of the technique. Several issues on implementation of the technique are also discussed.

1.0 Introduction

Breast cancer is predicted to be the second leading cause of death by cancer for American women, and the early detection of breast cancer is clearly a key ingredient of any strategy designed to reduce breast cancer mortality. Breast self-examination is the most cost-effective screening procedure available for early breast cancer detection. It is simple and non-invasive, and a large fraction of breast cancers are found by patients using this technique today. Although more than 300 scientific articles on BSE have appeared in the past ten years, they reveal a surprising lack of scientific data and objective evaluation.[1].

Clearly, traditional approaches to BSE is featured by their subjective nature. For BSE to be effective, the patient must use a proper search strategy to cover the entire breast region, but there is currently no objective clinical data in evaluating the effectiveness of a particular BSE strategy. Even if a particular strategy is determined to be the most effective, training a woman to use it is still difficult because there is no precise way for her to determine if she is doing correctly. Here we propose to build a system using vision-based motion tracking technology to gather quantitative finger-position data during the breast palpation process. By tracking the position of the fingers, the system could provide the first-hand objective quantitative data about the BSE process, which can improve our knowledge of the technique and help analyze its effectiveness. By displaying position features to the patient as the BSE is under way, the system could be used to give interactive feedback to the patient and create a prototype for a computer-based BSE training system.

While there exist other tracking technologies (e.g. magnetic, acoustic) which could be used to track the hand motion, vision-based tracking is considered the most appropriate for a

practical BSE data acquisition system because it is the least obtrusive and least expensive technique. Vision-based hand tracking is under investigation by many researchers[2-5]. Most of them use model-based method, in which 3D or even 2D models of a generic human hand are employed and fitted to the specific hand of a user for the tracking and recognition of 3D hand gestures. These methods are generally slow for real-time data acquisition so, for the specific situation of breast palpation, we propose a color-assisted finger tracking metaphor in this paper, which tracks the 3D spatial positions of colored finger nails. Color transform is utilized in color feature extraction, instead of directly using RGB values. Normalization of color attributes is used to tackle the problem of any possible minor ambient lighting variations. The relatively unchanging three-finger nail pattern is employed to differentiate the target fingers from any possible false patterns in the background. A pair of cameras are employed for stereo depth calculation, and the real-time performance can be achieved without using any special hardware.

2.0 Color-Based Tracking Approach

2.1 Color feature extraction

We propose to use colored finger nails and track the color features, because in breast palpation the background is the breast itself which is very similar to the hand in color. This special situation makes any other feature extraction techniques difficult to work correctly if real time performance is also required.

There are many color coordinate systems, such as RGB, HSI, LHS, YIQ etc. Each of them has its own advantages and disadvantages, and therefore they are selected and used according to the special requirements of the actual applications[6-8]. Basically, the color of a pixel in an image is initially represented as a vector of red (R), green (G) and blue (B) values. These values can be transformed in different color spaces like HSI, YIQ to get such values of the pixel as hue, saturation, luminance etc. Some of these transforms are nonlinear (e.g., HSI, LHS) and the others are linear (e.g., YIQ, XYZ). In practical applications, linear transforms are often superior to nonlinear ones because nonlinear transforms can result in some unexpected singularities[9]. In addition, if real-time performance is required, linear transforms are even more preferred because of their simplicities.

Unfortunately, color images captured by a camera are largely affected by the environmental lighting and shadowing conditions. The original color of an object is easily "hidden" by such factors as strong highlights and shadows, and therefore even the above-mentioned color transforms often have difficulties in removing these factors to get the real color values. This has invoked research into impacts of physical processes during the formation of an image on captured color properties, and recently color extraction and segmentation based on physical reflection models have been proposed, which can remove highlights and other factors from the image and which have shown better results[10, 11].

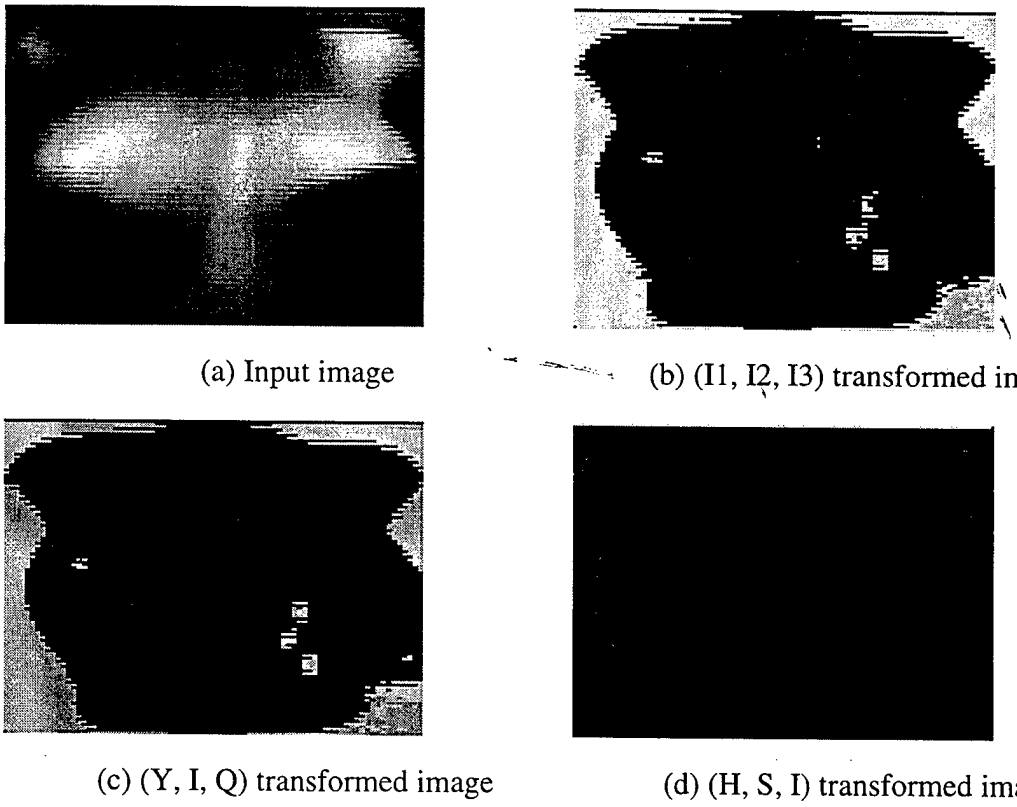
However, these methods are still in their early stage and are generally not so simple for real-time implementation, and therefore are not often employed in actual applications compared with those methods based on color transforms. Here we also make use of color transform and, after an experimental comparison of various coordinate systems, we select YIQ color space for color feature extraction in our system. We have compared three color spaces: (H, S, I), (I1, I2, I3), (Y, I, Q) which are defined as below.

$$
\begin{aligned}
H &= \arctan\left[\frac{\sqrt{3}(G-B)}{(R-G)+(R-B}\right] \\
I &= (R+G+B)/3 \\
S &= 1-\min(R,G,B)/I
\end{aligned}
\qquad (1)
$$

$$
\begin{aligned}
I1 &= (R+G+B)/3 \\
I2 &= (R-B)/2 \\
I3 &= (2G-R-B)/4
\end{aligned}
\qquad (2)
$$

$$
\begin{bmatrix} Y \\ I \\ Q \end{bmatrix} = T \begin{bmatrix} R \\ G \\ B \end{bmatrix} \quad \text{where } T = \begin{bmatrix} 0.299 & 0.587 & 0.114 \\ 0.596 & -0.274 & -0.322 \\ 0.211 & -0.523 & 0.312 \end{bmatrix} \qquad (3)
$$

Fig. 1 shows an example of the effects of the color transforms.



(a) Input image

(b) (I1, I2, I3) transformed image

(c) (Y, I, Q) transformed image

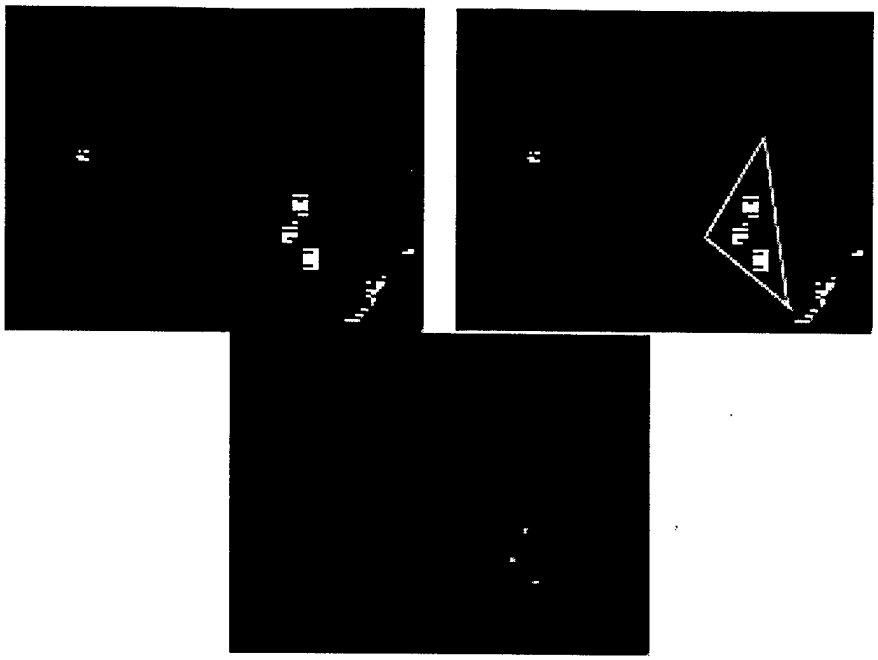
(d) (H, S, I) transformed image

Fig. 1 Comparison of different color transforms.

It can be seen that (H, S, I) is not robust to the noises in this situation, and both (Y, I, Q) and (I1, I2, I3) get satisfactory results. However, based on our experiments, (I1, I2, I3) transform is more sensitive to highlights than (Y, I, Q).

Although the environment is supposed to be well-illuminated, effect of minor changes in illumination is still considered using normalization of (R, G, B) vectors before color transform. Grouping of the extracted features is based on a principle of both distance and pixel numbers. That is, if the distance between two pixels is larger than a threshold, they are classified into different groups, and if a group has pixels of less than a default number, it is regarded as noise and therefore discarded. After grouping, if the group number is more than three, the three-finger pattern topology is checked for each group. This topology is in a small triangle pattern among

the centroids of every three groups, and each pair of the centroids should satisfy a distance constraint. This process is shown in Fig. 2.



(a) Extracted features (b) Grouping and three-finger pattern checking (c) Final finger positions

Fig. 2 Feature extraction and grouping.

Neighbor search is employed to ensure real time performance during the extraction of color features.

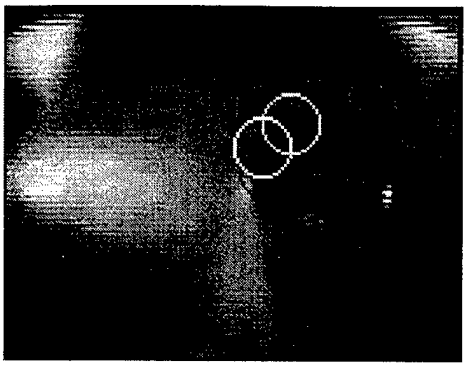
2.2 Position calculation by stereo vision

After detecting the features in the images, 3D position parameters of the colored fingers are calculated. In our experimental environment, the origin of a world coordinate system is set at the lens center of the left camera, and the x-axis is set across the two lens centers. The z-axis is set to coincide with the optical axis of the left camera. Suppose P(x, y, z) is the center point of a feature nail, and its projective projections on both the left and right camera images are (xl, yl) and (xr, yr), respectively, which are measured from image planes. Let d be the distance of the two cameras, and f be the focal length of the cameras, then the 3D position of P is calculated as follows:

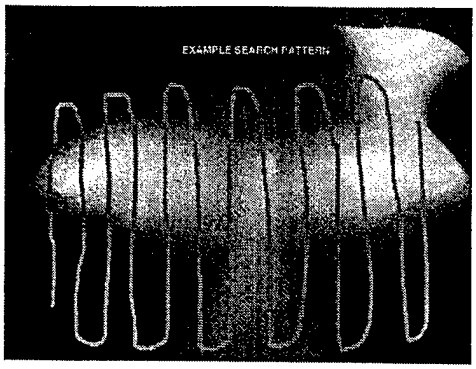
$$z = \frac{fd}{x_l - x_r} \quad x = \frac{zx_l}{f} \quad y = \frac{zy_l}{f}$$

3.0 Experimental Results

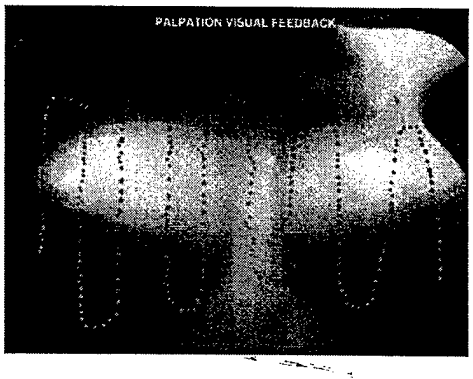
We have conducted experiments of finger tracking using the proposed approach, and a 15 frames/s performance is obtained using an image size of 160x120 and an Indy MIPS R4000 workstation. Finger 1 shows an example of the experiments. The system is quite robust and accurate in the experiments, which confirms the good performance and effectiveness of the proposed tracking approach.



(a) An example of real-time finger nail tracking



(b) Standard search pattern for breast palpation



(c) Visual feedback of finger positions

Fig. 3 An experimental example of finger tracking and visual feedback.

4.0 Discussion

In implementing the tracking technique and the system, the following issues have been considered.

(1) Tracking accuracy

The system can track a finger feature in an accuracy of about 3 mm (a pixel) when the cameras are placed at about 400 mm from the breast , which is much smaller than a finger itself.

(2) Obstruction

Because we are using a pair of cameras in tracking, total obstruction of both cameras is almost impossible to happen. However, when either camera is obstructed, depth information cannot be calculated properly. In such case, depth information will be estimated using projective scale changes.

(3) Interactive feedback

We are working toward two kinds of feedback. The first feedback is the touch-and-mark feedback, which marks, in real-time, each place on the real image of the breast as soon as it is touched by the fingers. In this way, a woman can clearly understand in real time where have been covered until now, and she can then plan a strategy for the next palpation. The system is now using this type of feedback. The second feedback is to visualize the recorded finger position data graphically in a 3D space. A woman can manipulate it using stereo glasses and spaceball

and can view it from arbitrary 3D angles. This will enhance her understanding of breast palpation mechanism and its importance.

(4) Low end system

Finally, the system is expected to be used by individual women at home for their convenience. The recorded data of palpation may be transmitted to physicians in the hospitals through the connections using telephone lines. These data can then be visualized in the hospitals and evaluated by the physicians. Comments will be sent back to the women for their improvements in breast palpation. To this end, we plan to implement the system in PCs to make it affordable as well as practical for most women.

5.0 Acknowledgement

It is greatly acknowledged that the phantom breast used in this research was provided by the WRS Group, Inc.

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Chapter 4

Telemedicine: Applications and Technologies

4.1 A Telemedicine Consultative Service for the Evaluation of Patients with Urolithiasis

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ABSTRACT

A six month pilot teleconsultative project linking Georgetown University Medical Center in Washington DC and City Hospital in Martinsburg, West Virginia 180 miles away, was designed to test a PC-based telemedicine platform for the evaluation of patients with urolithiasis. Videoconferencing and review of the patient's imaging studies was performed over ISDN (Integrated Service Digital Network) lines. The objective of this study was to establish technical performance requirements for evaluation of patients with urinary lithiasis and to assess the effectiveness of telemedicine on the clinical decision making process for these patients. There were a total of 32 telemedicine consultations; 14 in the clinical patient group and 18 in a simulated patient study group. The recommendation of the consulting urologist at the tertiary center was altered in 12 patients following the telemedicine consultation compared to the recommended treatment following the initial telephone consultation. This project allowed for immediate access and effective transfer of information between the referring urologist and the specialist. In addition, the telemedicine consultation enhanced the medical expertise of the referring urologist thus improving quality of care.

Key Words: telemedicine, urolithiasis, lithotripsy

1.0 Introduction

Telemedicine can be defined as providing medical expertise through the use of telecommunications and multimedia technologies. Due to ongoing technical advances in imaging, computers, multimedia, telecommunications and information systems, various telemedicine applications have become increasingly possible. At the present time, radiology is the only specialty with comprehensive standards in telemedicine (ACR). The American Medical Association has encouraged other medical specialty organizations to develop similar comprehensive standards (AMA). This pilot project was designed to evaluate the clinical effectiveness and technical requirements for a PC based telemedicine application in the evaluation of patients with urinary lithiasis. Telemedicine allows for consultation and clinically appropriate transfer of a patient with complex urinary stone disease to a hospital with specialists in the treatment of these patients.

The Center for Kidney Stone Disease at Georgetown University Medical Center (GUMC) was established in 1980 and treats more than 500 patients each year including a significant percentage of patient referrals and/or transfers from outside institutions. A well established referral pattern has been ongoing for the past six years between City Hospital in

Martinsburg, West Virginia (WV) and GUMC for treatment of patients with complex urinary stone disease.

Prior to the onset of the pilot study, the referring urologist would call and describe the clinical facts and the x-ray findings over the phone to the specialist at the stone center. In some cases, the initial recommendations were changed after the patients were seen in person and the x-rays reviewed first hand. For patients to obtain a consultation with the stone center, they must travel 180 miles or have their imaging studies mailed and wait several days for intervention. When calculi are associated with acute urinary tract obstruction, this delay in treatment is a significant hardship. Teleconsultation allowed for an immediate consultation and decision of appropriate treatment.

2.0 Materials and Methods

From October, 1995 to March, 1996 fourteen patients requiring consultation for complex and/or complicated urinary stone disease from the specialist at GUMC (JJP) were enrolled in this study. At the completion of the clinical trial, a simulated study was performed whereby 18 prior patients with urolithiasis, who the local urologist felt would have benefited from a telemedicine consultation were selected for review. To access the impact of telemedicine on the clinical decision making process, the consulting urologist at GUMC recorded treatment options following the 'usual' telephone consultation, following the telemedicine consultation and following examination of the patient if the patient was transferred to GUMC.

The telemedicine system was based on a Pentium PC platform with 32 Megabytes of Random Access Memory (RAM), Viewshare™ software (KLT Telecom, Inc., Chantilly, VA), a 2 Gigabyte hard drive, an audio/video codec (coder/decoder) board, and a video card with 1 Mbyte of memory to support an SVGA monitor with a resolution of 1024 x 768 x 8 bit color display. This interactive system allows for two-way color video and audio for remote consultation of the specialist at GUMC with the referring physician and/or the patient in their rural community, 180 miles away. Communications support included an ISDN (single Basic Rate, BRI Primary Rate, PRI) through an integrated Inverse Multiplexor (IMUX).

To incorporate the radiographic images into the telemedicine system the original studies were digitized with a laser film digitizer (Lumisys Inc., Sunnyvale, CA) at 2k x 2.5k x 8 bits matrix. The digitized images were optimized through software (model Photoshop, Adobe Systems, Inc., Mountain View, California), resized, and transmitted over 3 BRI lines and viewed on a 1024 x 768 x 8 bits monitor. To improve the digital image display of the radiographs, the PC version of OSIRIS, a free public domain software developed and distributed by the University Hospital of Geneva, was integrated to the platform.

Although review of the radiographs are an essential part of the telemedicine consultation for patients with urolithiasis; the primary focus of this study was not teleradiology. The original radiographic studies were interpreted by the radiologists at City Hospital prior to the telemedicine consultation. The urologist at GUMC reviews the radiographs with the referring urologist along with discussion of pertinent clinical information. The GUMC urologist subsequently recommends various treatment options with the final decision made by the referring urologist in West Virginia.

3.0 Results

Clinical patient group: The clinical consultations are summarized in Table 1. There were a total of 14 telemedicine consultations, 12 scheduled ahead of time and two emergencies. There were nine men and five women, 30 to 81 years of age. Following the telemedicine consultation, there were a total of five patient transfers to GUMC; two patients for percutaneous nephrolithotomy (PNL), one patient for flexible ureteroscopy and biopsy, one patient for bilateral extracorporeal shock wave lithotripsy (ESWL) and one patient for retrograde endoluminal ultrasound and endopyelotomy. The telemedicine consultations included ten patients with urolithiasis; renal calculi in five patients, ureteral calculi in four patients and renal and ureteral calculi in one patient. One patient had a radiolucent filling defect in the renal pelvis which proved to be a solid mass on ultrasound and not a calculus. One consultation was for follow-up after percutaneous nephrolithotomy and review of the nephrostogram. Two patients were evaluated for ureteropelvic junction obstruction.

The recommendation from the GUMC urologist was altered in seven patients following the telemedicine consultation as compared to the treatment plan following telephone consultation. These included one patient with renal calculi, one patient with ureteral calculi, one patient with both renal and ureteral calculi, one patient with a filling defect in the renal pelvis and the two patients with ureteropelvic junction obstruction.

Simulated patient study group: The telemedicine consultations for this group of patients consisted of 18 patients, 16 men and 2 women, 26 to 72 years of age. Of the 18 patients who had been previously seen by the referring urologist, seven were seen on an emergency basis and had an obstructing ureteral stone. The initial recommendation of the consulting GUMC urologist following the telephone conversation was changed in three cases after the telemedicine consultation. In these three cases, the recommendation of spontaneous passage was changed to ureteroscopy and stent placement, ureteroscopy and lithotripsy, and ESWL alone.

Ten patients were seen by the referring urologists as nonemergencies. Five of these patients had ureteral stones and the recommendation of the consulting urologist remained unchanged following the telemedicine consultation. The remaining five patients had renal calculi. In three patients there was no change in the clinical recommendation following telemedicine consultation. In one patient with bilateral renal calculi, less than one centimeter in maximum dimension, the initial recommendation for bilateral ESWL treatment was changed to medical treatment unless hematuria or pain subsequently developed. In one patient with a one centimeter uric acid calculi of the lower calyx, the initial recommendation of stent placement and cystoscopy was altered to medical therapy.

Table 1. *Summary of Clinical Patient Group Consultations*

Telemedicine session	Clinical; x-ray findings	Tx. plan after phone consult	Tx. plan after telemedicine consult	Tx. plan after transfer	Session type	Transfer to GUMC
1	calculus, 10x15 mm lower pole calyx	ESWL	ESWL		P	
2	calculus, 10 mm distal ureter	Ureteroscopy, ESWL	Ureteroscopy, ESWL		P	
3	recurrent UTI; calculus 30x18 mm renal pelvis	PNL	PNL	PNL	P	T
4	calculus, 6x8 mm lower calyx; crossing vessels	Renal scan with Lasix	ESWL		P	
5	UTI, positive blood culture; calculus, 25x15 mm renal pelvis	PNL	PNL	PNL	E	T
6	nephrostogram post PNL		continue follow- up WV urologist		P	
7	10 mm radiolucent filling defect renal pelvis	ultrasound recommended	flex. ureteroscopy	flex. ureteroscopy & biopsy	P	T
8	calculi, 8 mm UPJ, 8 and 4 mm distal ureter	PNL	ESWL		P	
9	calculi, bilateral 1-2 mm	Medical tx.	Medical tx.		P	
10	prior endopyelotomy, needs dilatation	Balloon dilatation & stent	Nuclear medicine renal scan, no tx.		P	
11	Calculi, 15x6, 15x12 mm bilateral upper ureters, 20x10 mm renal pelvis, severe obstruction	PNL	ESWL - bilateral	ESWL - bilateral	E	T
12	Calculi, 8mm UPJ, 8mm lower ureter, 4 mm UVJ	PNL	ESWL		P	
13	UPJ obstruction	Endopyelotomy vs. surgical repair	Endoluminal ultrasound	Endoluminal ultrasound, possible endopyelotomy	P	T
14	Calculus, 9x8mm mid ureter; ureteral guide wire perforation, stent in collecting system	leave stent in place x 10-14 days, then ESWL	Agree with pretele-medicine consult, KUB after ESWL, IVP after stent removal to R/O stricture		P	

Note: Tx. = treatment, ESWL = extracorporeal shock wave lithotripsy, PNL = percutaneous nephrolithotomy, UTI = urinary tract infection, UPJ = ureteropelvic junction, UVJ = ureterovesical junction, P = planned, E = emergency.

4.0 Discussion

Telemedicine can be defined as providing health care through a combination of telecommunications and multimedia technologies with medical expertise (Cabral). With ongoing technical advances in imaging, computers, information systems and telecommunications, multiple telemedicine applications have become increasingly possible. Telemedicine has the potential for improving access to care to rural areas or areas underserved by health care specialists or physicians (McGee), improve access to medical education (Lindsay), and to enhance the quality of care at an affordable cost. Current levels of activity suggest that telemedicine will become an integral part of medical practice (Rinde).

Prior to the integration of this telemedicine application, the West Virginia urologist would contact the GUMC urologist by telephone when consultation was needed for a patient with complicated urinary lithiasis or the need for PNL, a procedure not performed at the referring community hospital. Subsequently the radiographic studies were sent by federal express to the GUMC urologist or the patient traveled with the films themselves. With this telemedicine platform, the consulting urologist at GUMC has immediate access to the patient's images for evaluation and discussion of the treatment plan with the referring urologist and/or the patient. Relevant aspects of the images can be highlighted for clarification and the consulting urologist has the ability to annotate the treatment approach on the transmitted display of the radiographic studies.

Videoconferencing allows the patient and their family to 'meet' the consulting urologist and ask questions regarding treatment prior to transfer to the tertiary center, thus resulting in reduced patient anxiety. Patient's acceptability has been positive for most telemedicine applications (Yellowless).

Telemedicine provides an expanding pool of medical specialists available and allows the referring physician to have the advantage of a 'virtual' specialist level of expertise for consultation or review of a challenging case or a clinical case requiring transfer to a tertiary center. Recovery and follow-up of patients treated at the tertiary center can be provided at the medical facility in their home town through telemedicine as seen with consultation session number 6 in the clinical patient group.

For the tertiary centers, telemedicine consultation prior to transfer allows for better diagnostic preparation and more appropriate referrals. The patient's history, medical records, radiographic and laboratory studies, and pathology are received, examined and mutually discussed prior to transfer through the telemedicine consultation.

This study was limited to patients with urolithiasis to assess the effectiveness of telemedicine on the clinical decision making process for these patients. Of the 32 consultations in this study, 12 treatment plans were altered following the telemedicine consultation as compared to the initial telephone consultation. Similar results probably would have occurred with the traditional or pretelemedicine interaction, however telemedicine provided immediate access to the patient's imaging studies and relevant clinical discussion with the referring urologist and/or the patient themselves. Through the use of telemedicine, the immediate availability of a specialist improved the quality of care particularly in the emergency situation in patients with urolithiasis.

Teleducation was a valuable component of this pilot study. Throughout the six months, the referring and consulting urologists spent more time discussing the clinical case, treatment options, and final therapeutic decision during the telemedicine consultation as compared to the usual telephone consultation. Telementoring resulted in greater

confidence for the referring urologist in the decision making process. The simulated patient study group was performed at the completion of the pilot study. Greater concurrence of the decision making process was observed between the recommendations of the referring and consulting urologists, and this was felt to be attributed to educational component of this project.

As the referring clinicians became more experienced with the technology, additional applications were identified. During the six months of this project, there were several requests by the urologists and radiologists to apply this technology to other areas within urology as well as difficult neuroradiology studies. GUMC is presently considering a permanent telemedicine program with City Hospital once the clinical needs are formally established.

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4.2 Technical Requirements for Renal Dialysis Network

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ABSTRACT

The Imaging Science and Information Systems (ISIS) Center of the Department of Radiology at Georgetown University Medical Center (GUMC) has been developing technical requirements for different telemedicine applications. This paper details the process through which those technical requirements are determined and shows how technical requirements vary substantially depending on the clinical need. This is done in light of a nephrology application for renal dialysis patient monitoring we are currently undertaking at GUMC.

1.0 Introduction

Some applications within the telemedicine realm have come to a certain level of maturity such as teleradiology with established technical design parameters and specified guidelines (Mun, 1995, ACR, 1994). Other applications within telemedicine still need more definition. Grigsby et al have classified telemedicine applications as processes of care as opposed to viewing them within each subspecialty (Grigsby 1995). Very few studies have attempted to evaluate the technical efficacy and effectiveness of telemedicine systems based on PC platforms (Yamamoto, 1993; Yamamoto, 1994; DiSantis, 1987; Halpern, 1992). Although some evaluation methodologies have been described (Grigsby, 1995, Puskin, 1996), few have looked at designing and evaluating technical parameter requirements for telemedicine applications. At the ISIS Center of the Department of Radiology at GUMC, we are testing PC-based platforms for telemedicine applications used for different medical specialties. Our initial design revolved around a single architecture to serve all our applications including one for the management of patients with surgical stone disease (Tohme, 1996). With the addition of a new application based on renal dialysis patient monitoring, new clinical needs have prompted us to rely on a slightly different architecture to better suit those needs namely that of a multimedia database as well as the ability to download dialysis parameters and patient's health status from a distance. This is because several technical requirements were modified to suit the clinical needs of the nephrology applications which can be extrapolated to the management of patients with chronic illnesses.

2.0 Primary Technical Considerations

Varying technical requirements are expected to support different telemedicine applications. While there will be common areas for many applications, each specialty application will have its own unique requirements.

2.1 Technical Requirements Parameters

The technical requirements parameters to be evaluated with each clinical application differ along six major dimensions with each application relying on one or more of those dimensions. Figure 1 details the different technical requirements based on the three clinical applications. The various clinical applications can be grouped along six dimensions: motion video intensive, still video intensive, digital image intensive and diagnostic audio intensive, storage requirements and database requirements.
Motion video intensive applications refer to applications where the quality of the picture has to be of diagnostic quality and includes video input from clinical applications such as endoscopy and

ultrasound. In these cases, full motion video is important. MPEG2 and MPEG1 video compression algorithms can provide high resolution of up to 640x480. However, the high price of the encoders/decoders, extensive bandwidth requirements and the relative delay from compression algorithms make MPEG motion video compression not yet cost-effective. The use of ITU-T standard H.261 compression is the most common among video conferencing applications and can provide 320x240 resolution at Full Common Intermediate Format (FCIF).

Still video intensive applications include clinical applications that require frame grabbing capability to freeze frame motion video from medical scopes such as with otoscopes used in the Pediatrics project or dermascopes. Here images are captured, compressed for transmission using JPEG. Still video requiring higher quality can then be compressed using modified JPEG (MJPEG) or JPEG with low compression ratios. Frame grabbing video signals for transmission not only allows for greater resolution but also leaves larger bandwidth available for other video transmission.

Diagnostic audio intensive applications refer to applications where the diagnosis will be partly based on the audio component such as a remote stethoscope (nephrology) to monitor patient cardiac status. This places additional requirements in terms of bandwidth communications. Compressed audio may require anywhere from 64 to 128 Kbps of bandwidth. In our set up, stethoscope signals bypass the codec by using high quality audio encoders and decoders. The communication link between them is allocated separately on the T1 CSU/DSU.

Digital image data intensive applications are based on gray scale images and will have different requirements based on the modality, the clinical application and the primary operational setting (consultation or primary diagnosis). This type of data acquisition includes magnetic resonance imaging (MRI), computed tomography (CT) and radiology images obtained either through direct digital capture such as in computed radiography (CR) or through digitization techniques.

Storage requirements refer to short, medium and long term storage strategies used for the different applications. Finally depending on the nature of the clinical application, such as one for chronic illnesses, multimedia databases that can archive, retrieve and forward the different data types mentioned above is very helpful as will be discussed later.

2.2 The Common Platform Requirements

The common system requirements for our applications is a Pentium PC platform with 32 Megabytes of Random Access Memory (RAM), 2 Gigabyte hard drive, an audio/video codec (coder/decoder) board, a video card with 1 Mbyte of memory to support an SVGA monitor with a resolution of 1024x768x8 bits. Communications supported include ISDN (single Basic Rate, BRI, to Primary Rate, PRI) through an integrated Inverse Multiplexor (IMUX) or T1 (1.5 Mbps) through the use of a T1 board and a CSU/DSU (Channel Service Unit/Data Service Unit). Ancillary equipment that can be added depending on each application includes remote stethoscope, dermascope and other medical scopes (otoscope, endoscope, etc.).

3.0 Renal Dialysis Patient Management (RDPM) Network Platform

3.1 Clinical Rationale

Patients with uremia or End-Stage Renal Disease (ESRD) undergo hemodialysis, a mechanical process whereby blood is removed from a patient, cleansed of unwanted impurities and returned to them through vascular access, usually their forearm. Hemodialysis is the major form of renal replacement therapy for patients with ESRD and carries in the US a 22% first year gross unadjusted mortality, a figure which greatly exceeds that of Europe (14%) or Japan (12-14%) (USRDS 1995). Studies have suggested that the higher annual mortality rate for hemodialysis patients in the United States compared

with those in Europe and Japan is due to decreased dialysis time and inadequate dialysis dose (Hakim, 1992).

An increasing number of dialysis facilities are outpatient facilities situated at a distance from any physician and regularly staffed with nurses and technicians. Physicians make rounds on patients at variable intervals from weekly to monthly depending on the practice of the institution. The dialysis center that now is at GUMC, is moving to two off campus sites within Washington, DC. The Renal Dialysis Patient Monitoring (RDPM) network allows for remote patient monitoring of renal dialysis patients from a tertiary care center (GUMC) to one of the two off-site dialysis clinics.

Management of Routine Dialysis: At the beginning of a routine dialysis session, the technical/nursing staff examines each patient to determine vital signs and to seek evidence of pulmonary edema (detected by auscultation of the lung bases), cardiac abnormalities (heart rate and apical auscultation), and vascular access (graft or fistula) dysfunction - the latter by inspection and auscultation. Patients undergoing hemodialysis are usually dialyzed three times a week with each session lasting about four hours. At times patients frequently feel acute boredom and extreme restlessness. They often skip appointments and end dialysis sessions early.

Management of Emergencies: Renal dialysis patients commonly experience a variety of acute, chronic and emergency conditions requiring physician attention. Attending physicians may avoid some types of emergency with adequate longitudinal information consulted during patient rounds. This data is currently stored in various places throughout the medical center, not at the dialysis clinic. If emergencies or acute problems occur when the attending physician is off-site, it is impossible to provide real-time access to the patient or patient information needed to manage the situation. When the patients threaten to shorten their dialysis session, the physician cannot provide immediate reassurance or encourage them to complete dialysis.

In summary, the traditional renal dialysis service suffers from the following limitations:

- •Patient access to the physician is limited.
- •Physician access to patient data and the patient is limited.
- •Data necessary to manage the patients are widely dispersed.
- •Remote real-time acquisition and transmission of relevant data is not possible.
- •Physician is unable to reassure patients threatening to shorten their prescribed dialysis time

The RDPM network will have the following capabilities:

- Direct downloading of dialysis parameters[1] via the telemedicine system to a remote site.
- Digitization, storage and transmission to a remote site of patient charts, EKGs and lab results through a document camera. Storage in electronic patient folders for future consultation.
- Storage and retrieval of x-rays previously digitized at GUMC.
- Capture, storage and transmission of digitized audio from an electronic stethoscope.
- Live patient-physician interaction.

Patients report for regular hemodialysis treatment approximately three times a week. The routine clinical assessment includes :

- Cardiac, pulmonary and fistula auscultations. This is done through a stethoscope.
- Assessment of laboratory values (to include EKGs) mainly from patient charts.

[1] Dialysis parameters include automated patient blood pressure; venous pressure; arterial pressure; transmembrane pressure; blood flow rates; dialysate flow rates, conductivity, and temperature; ultrafiltration rates and sodium delivery.

- Evaluation of fistula through visual assessment as well as vascular ultrasound evaluation every three months to establish any shunt stenosis or narrowing.
- Patient/physician interaction.

The RDPM network will have the following capabilities:

- Direct downloading of dialysis parameters to the telemedicine system within the dialysis unit and from a remote site.
- Digitization, storage and transmission to a remote site of patient charts, EKGs and labs through a document camera and storage in their respective patient folders for future consultation.
- Storage and retrieval of x-rays previously digitized at GUMC.
- Capture, storage and transmission of digitized audio.

The patient will also have direct access to the physician for interactive video sessions whereby the physician will be able not only to monitor the dialysis parameters and examine the patient through remote auscultation but also discuss the patient's condition and care with him or her. By providing the ability to monitor one of the two dialysis clinics from an off-site location, the telemedicine system will allow the physician to monitor early signs of future emergencies.

Presently the dialysis center which is in the Georgetown University Medical Center, is moving to two off campus sites within Washington, DC. This creates an ideal opportunity to establish a Renal Dialysis Patient Management (RDPM) network exploiting the existing NII at the Georgetown University Medical Center. The RDPM network allows for remote patient monitoring of renal dialysis patients from a tertiary care center (Georgetown University Medical Center) to one of the two off-site dialysis clinics. The other site without the electronic link will be a control site.

3.2 Technical Requirements for RDPM Network Platform

While there will be overlap in the technical requirements for many telemedicine applications, some specialty applications will have their own unique requirements. The basic system components for our application is a Pentium PC platform with 32 Megabytes of Random Access Memory (RAM), a 2 Gigabyte hard drive, an audio/video codec (coder/decoder) board, a video card with 1 Mbyte of memory to support an SVGA monitor with a resolution of 1024 X 768 X 24-bit color display. Communications supported include ISDN (single Basic Rate, BRI, to Primary Rate, PRI) through an integrated Inverse Multiplexor (IMUX) or T1 (1.5 Mbps) through the use of a T1 board and a CSU/DSU (Channel Service Unit/Data Service Unit) . Ancillary equipment that can be added depending on each application includes remote stethoscopes, dermascopes and other medical scopes (otoscope, endoscope, etc.). In addition to the basic platform, the technical requirements can be grouped in terms of the data source characteristics (motion video, clinical still images, diagnostic audio, radiological images, and monitoring data) of the application as well as its requirements in terms of storage and multimedia database. The renal dialysis application is based on the Housecall™ 2.3 software (md/tv, inc., Maitland, FL).

3.2.1 Data Source Characteristics

Motion Video

The first type of data source we consider is the motion video as captured from a video input. All telemedicine applications use motion video, however some applications only require video conferencing quality while others include video input from clinical applications such as endoscopy and ultrasound and require diagnostic quality video. In these cases, full motion video (30 frames per second (fps) for National Television Standards Committee (NTSC) video) is important. The use of ITU-T standard H.261 compression is the most common among video conferencing applications and can process Full Common Intermediate Format (FCIF) pixel matrix of 352 X 288 up to 30 frames per second. However, this is not sufficient for compressing full NTSC signals which results in 544

(Nyquist sampling) pixels, 480 lines and 30 fps (Chen 1996). In this case, Motion Picture Experts Group (MPEG) video compression algorithms (EGFF, 1994) provide an alternative for high resolution video with MPEG1 supporting lower resolution sequences (requiring up to 1.5 Mbps) and MPEG2 supporting higher resolution sequences such as video broadcasting (requiring up to 10 Mbps). However, MPEG motion video compression adds a delay from compression algorithms and has extensive bandwidth requirements (MPEG2). Furthermore, the high price of the encoders/decoders make this type of video compression not yet cost-effective. In the RDPM network, motion video will be used for videoconferencing purposes including patient to physician interaction at the time of emergency. However, it will also be used as a diagnostic tool not only for the evaluation of the fistula but also for edema, skin diseases, etc. If H.261 compression does not prove to be clinically satisfactory in the RDPM network then MPEG algorithms will be considered.

Clinical Still Images

Clinical still images include clinical applications that require frame grabbing capability to freeze frame motion video from video cameras or medical scopes such as with otoscopes, opthtalmoscopes or dermascopes. Here images are captured, stored at 640 X 480 X 24-bit color and later compressed for transmission using JPEG (Joint Photographic Experts Group) compression algorithm. Because JPEG compression is a lossy algorithm, clinical still images requiring higher quality can be compressed using JPEG with low compression ratios. In the renal dialysis application, clinical still images are used for capturing stills for fistula evaluation (Figure 1) through a video camera (model VC-C1™ MKII, Canon USA Inc.). A document camera (model Vizcam™ 1000, Canon USA Inc.) is also used to capture EKGs and laboratory reports.

Diagnostic Audio

Diagnostic audio intensive applications refer to applications where the diagnosis will be partly based on the audio component such as a remote stethoscope (nephrology) to monitor patient cardiac status. This places additional requirements in terms of bandwidth communications. Compressed audio may require anywhere from 64 to 128 Kbps of bandwidth. In the renal dialysis set up that uses diagnostic audio, stethoscope signals bypass the codec by using high quality audio encoders and decoders. The communication link between them is allocated separately on the T1 CSU/DSU. The requirements for diagnostic audio are relevant to the renal dialysis application where the nephrologist will assess the patient cardiac and pulmonary status once a week for routine cases. Remote stethoscope is also used for fistula evaluation and is performed at the beginning of a session for routine cases.

Radiological Images

Radiological image intensive applications use gray scale images and will have different requirements based on the modality and the clinical application (consultation or primary diagnosis). This type of data acquisition includes magnetic resonance imaging (MRI), computed tomography (CT) and conventional radiology images obtained either through direct digital capture such as in computed radiography (CR) or through film digitization techniques.

In the renal dialysis application, radiography and ultrasound are used to detect both acute and chronic complications of dialysis treatment. For dialysis centers separate from a hospital, there will be a need for intermittent radiographic and ultrasound examinations to evaluate acute symptoms. These studies will be done at GUMC and the images will be made available on the network.

Monitoring Data

This type of data refers to alphanumeric patient data downloaded to the telemedicine system. This can refer to patient vital signs (blood pressure, heart rate, respiratory rate, temperature) and/or application specific data such as the dialysis parameters described earlier in the renal dialysis application. The dialysis machines (model 2000, Fresenius Inc., Concord, CA) in each hemodialysis

center are connected to a central PC workstation where the dialysis parameters are downloaded. In turn, this PC platform is connected over a serial interface (RS232) to the Housecall™ 2.3 software of our telemedicine workstation. The dialysis parameters can then be retrieved either on a real-time basis or on a historical basis for a specific patient given a pre-specified time period.

3.2.2 Storage and Multimedia Database Requirements

In the renal dialysis application, since patients are to be followed over many years, the amount of data becomes very important. Therefore, storage issues for the RDPM network had to be approached differently. Research data acquired from the RDPM network will be stored in a WolfCreek tape library system (StorageTek Inc., Boulder, CO). The Multimedia Medical Image Archival and Retrieval Server has been installed at the ISIS Center to provide medical data records. In the dialysis application, the medical data includes text (text report and patient demographic information), images (screen films, radiography, CT, US), sound (digital stethoscope), and video (digital US and telemedicine consultation). All the medical data is keyword indexed using a database management system and can be placed in a staging area temporarily and then transferred to an 800 GByte tape library system for permanent storage. When the patient is evaluated through video and remote auscultation, the data will be transmitted and stored at the physician's site. Once a week for routine cases, the nephrologist decides which portion of the auscultatory findings for cardiac and pulmonary assessment will be recorded and stored in the patient's folder. The fistula still video will be captured once a week per patient and will be stored in the patient folder. In order to accommodate the storage and archival requirements of the longitudinal patient study, additional storage will be provided through an external hard drive and/or zip drives and/or optical read/write compact disks. Long term storage will be provided on the tape library system.

Although a multimedia database can be useful for any telemedicine application, some applications will find a greater need for it than others. The dialysis application is representative of a telemedicine application requiring a multimedia database for diagnostic audio, radiology images and clinical still images. By having easy access to the patient's clinical history in the form of a multimedia data folder with diagnostic audio (stored heart, fistula and lung sounds), still video (fistula), digital diagnostic images (chest images, ultrasound images and CT images), motion video (physician/patient interaction), and present and past clinical chemistries and hematologic indices, the physician at GUMC will be able to compare past values with current ones. Our renal dialysis telemedicine platform is based on a relational SQL database and is presented to the user as contained within a graphical patient folder. There is a master folder for each patient representing all data about the patient and a session folder representing data from each session. The system is also capable of recording, storing and forwarding full motion video (up to 640 X 480 X 24-bit color X 30 fps) and audio, still video (frames grabbed at 640 X 240 X 24-bit color), digital audio stethoscope (16 bit, 44 Khz).

4.0 Conclusion

Through the use of an integrated PC-based platform, several telemedicine applications are being undertaken by the ISIS Center at GUMC. While there will be overlapping requirements for many applications, many specialties will have unique requirements. In light of an application that the ISIS center is undertaking, this paper explains the differences that may arise between telemedicine applications in terms of the type of data that is involved as well as the storage and database requirements. The first application, a urology based application, involved the transmission, viewing and manipulation of radiological images as well as patient/physician interaction. The renal dialysis patient management network has introduced new technical requirements. The main issue, not previously addressed by our other telemedicine platforms, was the longitudinal nature of the application where patients need to be followed over years. To implement this system required a different solution that included long-term storage and a comprehensive multimedia database. This

paper details these differences and shows how the introduction of each new application must be analyzed to be certain that the technology can satisfactorily meet the needs of the health care providers.

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4.3 The Effects of Motion JPEG Compression on the Diagnostic Quality of Pediatric Echocardiograms

Primary Investigators

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ABSTRACT

Congenital heart disease is infrequent and often is apparent in the immediate newborn period. Rapid excellent diagnosis is important to provide appropriate care to avoid patient morbidity and mortality. Color flow Doppler echocardiograms are an essential part of the diagnostic assessment of the newborn however few hospitals have the staff to interpret these studies appropriately. Transmission of these studies to a regional center with subspecialists will allow interpretation of the studies by physicians with expertise in this subspecialty. Devising an inexpensive, high-quality telecardiology system allows physicians to appropriately and rapidly triage neonates with high-risk congenital heart disease. To make a telecardiology service affordable in the near future, the 73 million bit per second (Mbps) transmission speed must be reduced to affordable bandwidths using compression. The purpose of this study is to evaluate the impact of motion Joint Photographic Experts Group (motion JPEG) on the diagnostic quality of pediatric echocardiograms.

1.0 Introduction

Congenital heart disease is infrequent (6-7/1,000 live births) and often is apparent in the immediate newborn period (65% of cases). Rapid excellent diagnosis is critical to provide appropriate care to avoid morbidity and mortality from major forms of congenital heart disease. Color flow Doppler echocardiograms are an essential part of the diagnostic assessment of the newborn however few hospitals have the staff to interpret these studies appropriately. Transmission of these studies to a regional center with pediatric cardiologists will allow for expert consultation and recommendations by subspecialty physicians and appropriate triage of patients.

Populations of children who are now usually seen by pediatric cardiologists include the major groups below:

TABLE 1
Children with Congenital Heart Disease:

Caseload of Children with Congenital Heart Disease
Diagnosed in Infancy/100,000 Live Births
Data from the Baltimore Washington Infant Study

Diagnosis	Occurring As An Isolated Malformation	% of Cases	% cases operated as infants at <1 yr. old
Aortic Stenosis	81%	3	47%
Atrial Defect	70%	8	8%
AV Canal Type Defect	21%	8	58%
Bicuspid Aortic Valve		2	10%
Coarctation of Aorta	74%	5	73%
Single Ventricle (LV)		0.4	67%
Double Outlet RV	61%	2	65%
Heterotaxy	20%	2	39%
Hypoplastic Left Heart	83%	4	34%
Interrupted Aortic Arch		1	77%
l-Transposition		1	70%
Pulmonary Atresia	90%	2	79%
PDA	68%	3	55%
Pulmonic Stenosis	87%	9	12%
Total Anomalous PVR		1	92%
d-Transposition	89%	5	83%
Tetralogy of Fallot	65%	7	59%
Tricuspid Atresia		1	69%
Truncus Arteriosus	63%	1	63%
Ventricular Septal Defect	81%	34	13%

The twenty cardiac diagnoses shown in the table above represent 95% of all infants diagnosed at less than one year of age, thus in the nine years of the Baltimore Washington Infant study, 4390 cases of infants with congenital heart disease were identified. In the first year of life 35% of infants undergo some surgical procedure. The death rate for medically treated infants is 13% in this year and for surgically treated infants 23%; probably due in part to prematurity, low birth weight, intrauterine growth retardation and associated malformations.

Published incidence figures for CHD are 7-8/1000 live births; the reported diagnoses under 1 year are about 65% of that. However, from 1981 to 1989 diagnosis occurred earlier in life due to the use of color flow echo. The incidence of some diagnoses such as familial hypoplastic left heart decreased probably due to fetal diagnosis. It is likely that a greater population of surgeries will arise from cases diagnosed in the first year of life than from cases diagnosed later.

For a population of 100,000 live births one can anticipate 488 new cases of CHD diagnosed in infants per year; these 488 cases will generate approximately 2670 surgeries per decade or 267 surgeries per year. Congenital heart disease occurs in a setting of multiple

malformations, chromosomal anomalies, prematurity, low birth weight and /or intrauterine growth retardation in at least 20% of infants. Of 800 infants born with congenital cardiovascular malformations 18% would be expected to die in the first year of life, leaving 656 survivors at the beginning of year 2. For a given infant born with CHD, the probability of surgery is estimated to be 6.7%/year for the first decade. Thus for a hospital with 5,000 live births yearly one can anticipate 24.5 cases of congenital heart disease of whom 13 will require surgery. This case load presents the hospital with a difficult diagnostic problem in that they must be able to screen a large number of births to identify the few infants for whom early identification is crucial to survival.

Within the last decade, the numbers of infants with minor/mild congenital heart disease identified under 1 year of age has increased dramatically, i.e. a greater than 10 fold increase in the numbers of infants with muscular ventricular septal defects. Pulmonary stenosis and membranous VSD, have also increased. This increase is attributable to the use of color flow echo in part: e.g. the diagnosis of pulmonary stenosis increased but the number of infants requiring cardiac catheterization or surgery remained constant. Examples of these increases in diagnostic frequency are shown in Table 2. The 1582% increase in muscular ventricular septal defects is not accompanied by a similar increase in candidates for surgical treatment of this problem. Most centers report reductions in severe congenital heart disease over the last one to two decades due to improved fetal diagnosis and parental choice of termination of such pregnancies. This is consistent with the reported reduction in cases of hypoplastic left heart syndrome, looping defects, and pulmonary atresia in the data below. The implication of the vast increases in some other diagnoses is that the population of infants with congenital heart disease includes a subset who have mild, non progressive cardiac disease.

TABLE 2

Diagnosis	Cases in 1989 as a Percentage of Cases in 1981
Looping defects (e.g., Asplenia, Polysplenia)	63%
Transposition of Great Vessels	94%
Tetralogy of Fallot	206%
Atrioventricular Septal Defects	132%
Pulmonary Atresia	88%
Hypoplastic Left Heart	63%
Coarctation of the Aorta	122%
Pulmonary Stenosis	311%
Atrial Septal Defect	248%
Membranous Ventricular Septal Defect	199%
Muscular Ventricular Septal Defect	1582%

Telemedicine evaluation of echocardiograms of infants and newborns is an optimal technology for improving management of neonates. Small communities and small hospitals do not have the population of births to support pediatric cardiology services or echocardiographic assessment of infants in a timely fashion. It is estimated that a population base of 300,000 individuals is necessary to provide clinical material for one pediatric cardiologist in practice. Thirty-five percent of congenital heart disease diagnoses are likely to present in the immediate newborn period including complete atrioventricular canal, single ventricle, double outlet right ventricle, heterotaxy syndromes, hypoplastic left heart, interrupted aortic arch, pulmonary atresia, total anomalous pulmonary venous return, d-transposition of the great vessels, Tetralogy of Fallot and tricuspid atresia. In addition, one third of aortic stenosis, one third of pulmonary stenosis and approximately half of all ventricular septal defects are apparent in the immediate newborn period. Including these cases, 55% of congenital heart disease diagnoses in infancy would be apparent in the newborn period. These cases are all readily confirmed by review of

echocardiograms recorded using real time color flow Doppler echocardiography equipment which is readily available in community hospitals. Technicians can be trained to record the appropriate views for pediatric patients in a standard fashion.

Telemedicine in cardiology

Transmission of echocardiograms via satellite in a real time interactive fashion, allowing consulting physicians to discuss the study in progress with the referring physician and ultrasonographer, has been used in Oregon and Washington state and reported by Dr. David Sahn (personal communication). The Department of Pediatric Cardiology at the University of Louisville School of Medicine has evaluated transmissional echocardiographic studies by creating two quad-screen, cine-loop echocardiogram studies from rural sites where the University has clinic presence on an intermediate basis (Sobczyk). One cine-loop includes two-dimensional images from the parasternal long- and short-axis views, an apical or subcostal four-chamber view, and a suprasternal view of the aortic arch and a second loop with the addition of color flow Doppler. Results of 47 studies showed 39 (87%) to give accurate diagnostic impressions compared to videotape review. Only 1 (2%) of 47 studies resulted in an inappropriate clinical decision with a delay of one day for patient transfer. Transmissional echocardiogram evaluation resulted in no inappropriate therapy and no inappropriate transfers. Similar results were reported for a 30 month period of direct neonatal echocardiography transmissions to University Laval in Quebec, Canada from a peripheral center 180 miles away (Cloutier). In this study, 31 infants were evaluated allowing medical treatment prior to the transfer of three infants. Transfer of 28 infants was avoided due to confirmation via neonatal echocardiography transmission of a normal heart or a benign defect.

A prototype cardiac image network using Asynchronous Transfer Mode (ATM) networking has been successfully implemented with a scaleable approach to real-time cardiac image review over local- and wide-area networks (Elion). This technology permits diagnostic-quality full-motion cardiac studies to be accessed and integrated with archived multi-modality image data at distributed sites.

Two studies have reported their results in the evaluation of the electronic stethoscope for pediatric telecardiology. Mattioli et al (Mattioli) reported sensitivities and specificities of 80% and 90% respectively in a preliminary evaluation of remote electronic stethoscopy in seven children with cardiac murmurs. Belmont et al (Belmont) found an 89.5% overall screening accuracy when comparing the telestethoscopy with the standard acoustic stethoscope as a reference in 38 cardiology outpatients.

Pediatric Cardiology Services at Georgetown University Medical Center

The Division of Pediatric Cardiology at Georgetown University Medical Center (GUMC) provides clinical services in Annandale, Virginia (VA), Gaithersburg, Maryland (MD), Anacostia, DC, Waldorf, MD, Annapolis, MD, Ballston, VA, and Greenbelt, MD, in addition to GUMC. The faculty also provides consulting services at area hospitals including Sibley Hospital, Columbia Hospital for Women, and Greater Southeast Community Hospital in the District of Columbia; Anne Arundel Hospital and Washington Adventist Hospital in Maryland; and Alexandria Hospital and Arlington Hospital in northern Virginia. Consultations are also received from more distant sites from Manassas and Winchester, VA and Leonardtown, MD.

2.0 Experimental Design

Technical

With the recent telecommunications rulings, the industry is due to change the nature of what services are available to areas of the nation. The radical change in telecommunications offerings and tariffs in North Carolina are an indication of the future of the industry. Thus, the tariff for a T1 (1.544 million bits per second) service of two years ago is more than five times the cost of the present identical service in an area utilizing Asynchronous Transfer Mode (ATM) services. Furthermore, the OC-3 (155 million bits per second) ATM service is roughly the cost of that T1 service two years ago. This is more than 100 times the service at the same previous cost.

The future will include applications utilizing their services which are becoming more affordable. We will test applications which can reside on T1, and ATM access at either 10 Mbps or 45 Mbps. The access to such communication services with the current generation of digital information-processing equipment will have a change on the delivery of health and human services throughout the nation.

To make a telecardiology service affordable in the near future, the 73 million bit per second (Mbps) transmission speed must be reduced to affordable bandwidths using compression technology developed by motion Joint Photographic Experts Group (motion JPEG). Initially we will study the feasibility of T1 service, ethernet service (becoming commercially available in areas), DS-3 service, and OC-3 service. Once the proper bandwidth is determined, a prototype network will be set up. Preliminary data indicates that about 10 million bits per second (Mbps) is needed for a proper 30 frame per second presentation of pediatric echocardiograms. Echocardiograms will be compressed using motion JPEG.

Four randomized levels of compression supporting the following transmission bandwidths will be evaluated on thirty selected echocardiograms studies on S-VHS format:

- 1:1 which in no compression. This roughly corresponds to the OC-3C service
- 1.4:1 which roughly corresponds to the DS-3 service
- 6.3:1 which roughly corresponds to the ethernet speed ATM service
- 41:1 which roughly corresponds to the T1 service

This is done using the Quality Factor of the ATM CODEC.

Interpretation

Blind readings of the 30 echocardiograms each compressed at four levels and a control will be performed by five pediatric cardiologists. Echocardiograms for interpretation were selected from clinical practice at Georgetown University Medical Center by one of the authors (KSK). The thirty studies consist of both normal echocardiograms and cases of congenital heart disease. The order of cases was randomized and the experiment will be designed so that each patient is assessed by each cardiologist in only one of the five compression rates. No history was provided to the readers.

Interpreters were assigned confidence ratings of not identified; poorly identified non-diagnostic; fair identification, possibly diagnostic; good demonstration, probably diagnostic; and

excellent demonstration, highly diagnostic for the purpose of ROC analysis to the identification of 21 cardiac structures including Doppler tracing. Primary cardiac structures such as atria, ventricles, aorta, pulmonary artery, valvular structures, etc. as well as more subtle structures, such as the Eustachian valve and the left coronary artery bifurcation were included for identification. For interpretation of the diagnosis, interpreters were assigned confidence ratings of definitely normal, high confidence; probably normal, moderate confidence; indefinite, low confidence; probably positive, moderate confidence; and definitely negative, high confidence for the purpose of ROC analysis. Each interpreter was asked to list the leading three diagnosis for each study. The resulting analysis will then enable the comparison of compression rates across raters and patients.

3.0 Results and Conclusion

The present status of this study is in the interpretation phase. Compression of the 30 echocardiograms has been completed. The five pediatric cardiologists are currently interpreting the echocardiograms at the various compression rates. Following data analysis, recommendations for the bandwidth requirements for transmission of high-quality echocardiograms to a regional center with subspecialists will be finalized.

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4.4 Medical Image Archive and Retrieval System

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ABSTRACT

A Medical Image Archive and Retrieval System (MIARS) has been developed and installed at the Imaging Sciences and Information Systems Center at the Radiology Department of Georgetown University to provide a long term storage function for both researchers at Georgetown University and other institutions. The system acts as an Internet server to allow users access from anywhere on the Internet. Users can store, retrieve, and update images using a general purpose Internet browser and Java programs. The system contains x-ray images from computed radiography, MRI, computer tomography, and ultrasound. Other images include still video from telemedicine consultation and color pathology images.

1.0 Objectives

The purposes for the system development are to:

- provide researchers a user friendly interface to store, retrieve, update, and delete various types of image files.
- provide a cost effective near line storage system for long term data archives.
- provide an on-line staging system for fast retrieval.
- provide security measures to protect the data integrity and the patients' privacy.

2.0 Hardware and Software Configurations

The following is the list of hardware in the system:

- Wolfcreek 1000 tape library module with robotic arm
- Two 9490 high speed tape drives
- Sun Sparc 5 station
- Sun Sparc 20 station

The following is the list of software in the system:

- Wolfcreek internal database system
- ACSLS Wolfcreek controller module
- Enterprise Volume Manager (EVM) to manage tape library
- Solaris 2.4 OS for Sparc 5 and Sparc 20 stations
- Netscape Communications Server
- Java Development Kit 1.02
- Sybase SQL Server 10
- Netscape internet browser
- MIARS software (MIS, MIR, staging manager, FTX)

3.0 System Components Description

The basic MIARS provides data archival and retrieval services for researchers to perform image classification and Computer Aided Diagnosis (CAD) research. Additionally, it will provide backup services as an option for all workstations' local disks on the ISIS center TCP/IP Local Area Network (LAN). The client's retrieval and display provides a graphical user interface (GUI) for displaying a list of images, and provide simple text-based searches for images. The MIARS will provide the client's GUI to support the image ingest process. All image ingestion processes will be done manually by entering the source of the image filename and metadata associated with the image through a MIARS graphical user interface. The images stored in the MIARS will be in compliance with the DICOM standard, i.e., images and metadata will be stored in the form of DICOM objects. This design allows for the future implementation of full DICOM compatible services. There is no image compression/ decompression will be performed by the MIARS software, there will be a native compression when storing data into tapes.

4.0 Function Description

There is client software running on the user's workstation to provide GUIs to handle both ingest and retrieval functions. In addition, there is server software running on the application server (a Sun Sparc 20) to perform patient identification extract image data and interface with a relational database SYBASE, and the StorageTek ACSLS/EVM server. The SYBASE database will maintain tables relating to patients, studies, exams, and other metadata and images. There will be a mandatory association between an image and a patient. The ACSLS/EVM server is a Sun Sparc-5 used to control the StorageTek WolfCreek 1000 library. Finally, the staging disk manager software will be implemented by Loral to provide transfer to and from the staging disk. Detailed subsystem descriptions are summarized as follows:

4.1 Medical Image Storage (MIS) client

The client software provides the menu for entering all image file names, image formats and metadata for storage. The client software opens a socket connection to the MIS server and transfer the image file and associated data to the server. The server informs the client of the storage process status.

4.2 Medical Image Storage (MIS) server

The server software runs on a Sun server as the host of the StorageTek tape library system. The server waits for socket connections from clients and performs the following functions.

4.2.1 Extract image data

This module is triggered by the storage message from the MIS client. It extracts patient identification data and receives image pixel files.

4.2.2 Patient identification

This module matches the extracted patient ID from 2.2.2.1 with the patient's Universal ID (UID) stored in the patient database records If the match is successful, the patient's record is updated for new images. If the match files, a new record is added to the patient database and a new UID is assigned to the patient.

4.2.3 Assign a file name
This module assigns the patient ID, study ID, series ID and date/time as a file name for the series. The images can be grouped as a subset.

4.2.4 Update database
This module stores the user entered image metadata information into the metadata database. Embedded SQL is used to interface with the database management system (DBMS).

4.2.5 Write to tape library
This module uses the StorageTek EVM API to write the image file to the tape as a DICOM object. The format of the DICOM image IOD is preserved so that the IOD can be retrieved without reformatting.

4.3 Medical Image Retrieval (MIR) client
The MIR client provides GUI displays. It also provides the sure with the capabilities to enter the patient's name and identification number, image type, image date and other appropriate information for image retrieval. The client software makes a socket connection to the MIR server to sent the retrieval request and waits for the retrieved information. The client provides the capability to store the retrieved information in a user selected file directory.

4.4 Medical Image Retriever (MIR) server
Upon receiving retrieval or query requests from the MIR client, the server performs the following functions:

4.4.1 Extracts the search keys
The server extracts search keys, such as patient name, ID number, image type, modality type, date, etc. from the request message.

4.4.2 Formulate SQL statement
The server generates an SQL statement from the search keys and the database schema informational The SQL statement is used to retrieve the image file names and associated metadata satisfied by the search keys. The server informs the client of the number of images satisfying the search and waits form the client's order to proceed reading image files from the tape library.

4.4.3 Read the image file from tape library
The server uses the retrieved file name to read the image from the tape library The image file and metadata are sent back to the client as requested.

4.5 Staging disk manager
The staging disk manager manages the image files on the staging disk. It monitors the staging disk space periodically and deletes old and unused files as needed. All files retrieved from the tape library are kept on the staging disk until deletion. The DBMS has all image file information on the disk for quick retrieval. GUI displays are available for the operator to configure the staging disk deletion policy and display disk status information.

5.0 SUMMARY

The MIARS provides a centralized data repository for the researchers within the department and from other institutions. It will also be a medium for exchange information with researchers from other universities. MIARS will provide the researchers a cost-effective and user friendly permanent multi-media file archive system.

4.5 Evaluation Platform for a Clinical Pharmacology Application

Primary Investigators

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ABSTRACT

The Imaging Science and Information Systems (ISIS) Center of the Department of Radiology at Georgetown University Medical Center (GUMC) is undertaking several telemedicine projects within the medical center to evaluate the effectiveness of telemedicine for various clinical applications. We are testing PC-based platforms for telemedicine applications used for three different medical specialties with the Departments of Surgery, Medicine and Pediatrics. These are the first three projects among a number of forthcoming ones with various clinical departments at GUMC. The main goal of our efforts is to establish the necessary technical performance requirements for each clinical application.

1.0 Introduction

At the ISIS Center of the Department of Radiology at GUMC, we are testing a PC-based platforms for telemedicine applications used for different medical specialties. This paper describes the technical requirements and evaluation methodology used in the project undertaken with the Clinical Pharmacology Division of the Department of Medicine.

Telemedicine Technology Assessment and the Iterative Process of Continuous Quality Improvement

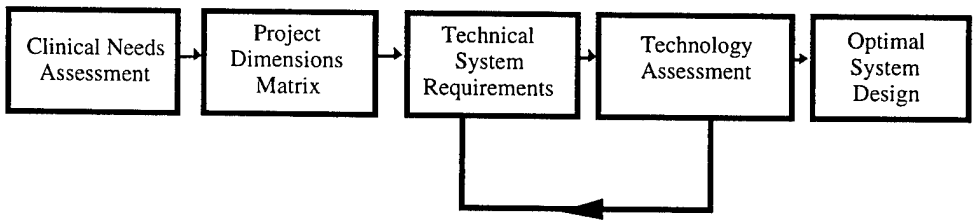

Figure 1

Our approach to the evaluation process starts with a clinical needs assessment (Figure 1). Applications are then selected based on those needs and on specific characteristics of the clinical application. This is done through a multidimensional matrix representing the different aspects of each project. Based on this matrix and the clinical scenario, the technical system design parameters are developed. This is followed by an iterative process of assessing the technology and feeding back this information to the system design until the optimal system design for each clinical application is developed. This paper elaborates each step of this approach in light of the clinical pharmacology project that the ISIS Center is undertaking.

2.0 Clinical Needs Assessment

Our telemedicine projects stem from an existing clinical need. Assessing this need is the first step in each project. The appropriate sophistication level of technology can then be selected and the project can be built to satisfy those needs and allow for future growth and appropriate utilization.

This application investigates the usefulness of telemedicine in providing a clinical pharmacology consultation service between the consultant in the Department of Clinical Pharmacology and the internal medicine resident at a distant location. The need is based on the increasing challenge of maintaining a high quality education in the principles of rational therapeutic decision making. New educational models are required to maintain a high quality education in the principles of therapeutic decision making as training programs move toward multiple ambulatory care sites. Telementoring to multiple sites potentially increases faculty efficiency and emerges as a promising new model. The goal is to evaluate the impact of telemedicine on the medical decision making process for residency training. The physician is directing the resident or the student from an off-site location on how to proceed with the clinical care of the patient. The consulting physician also has the opportunity to discuss the clinical case and evaluate the patient through the telemedicine system.

Telemedicine for Clinical Pharmacology
Clinical Pharmacology Consultation Service from an Off-Site Location

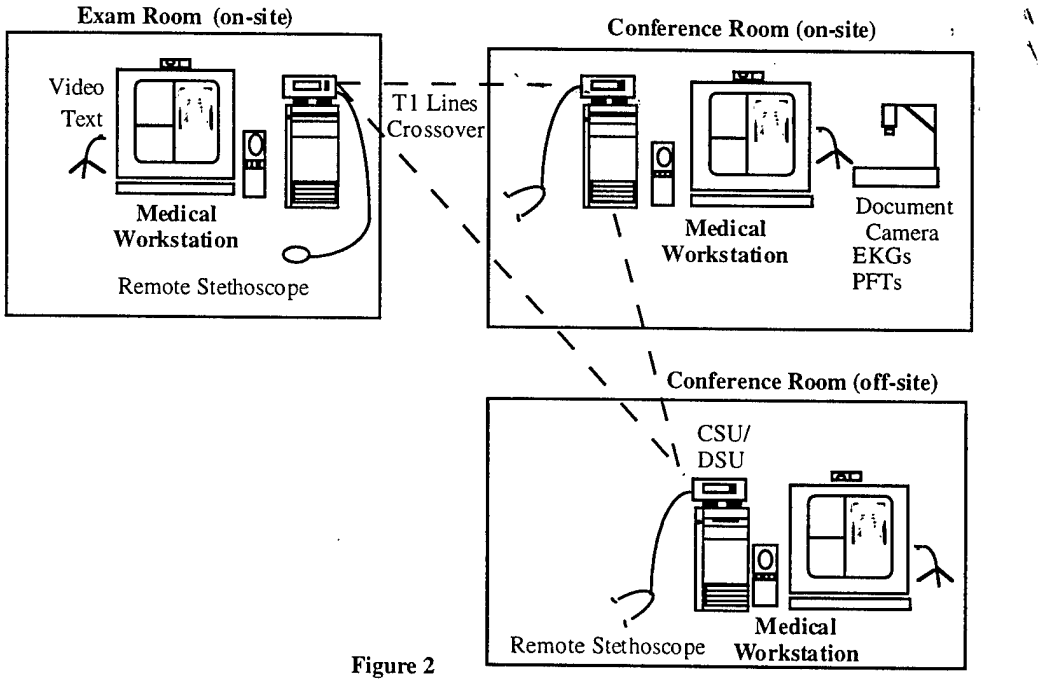

Figure 2

3.0 Defining a Multidimensional Matrix for Project Selection

Once the clinical need is established, the projects are then selected based on their uniqueness and their future applicability to other clinical situations. This is done through a multidimensional matrix where each project is selected based on several dimensions (Table 1). This matrix is likely to grow, expand and be transformed as new projects are added or new dimensions are examined. For the present time, we have selected five dimensions for our project.

Table 1
Project Dimension Matrix

Clinical Application	Communication Paths	Project Scope	Geographical Setting	Impact of Interest	Operational Setting
Clinical Pharmacology	Specialist-Resident/ Medical Student	Telementor-ing	Intra-Hospital	*Educational *Subspecialty Consultation	Scheduled Consultation

Communication paths in this application is from specialist to resident or medical student and the project scope is telementoring. Geographical settings raise the issue of medical licensure and credentialing for interstate projects. However, since this project is undertaken within GUMC, this is not an issue. The impacts of interest include various outcomes requiring assessment. The Clinical Pharmacology project is interested in the utility and efficacy of a multi-site educational effort and is predominantly scheduled consultation .

4.0 Technical System Requirements

Our telemedicine system is based on a Pentium PC platform with 32 Megabytes of Random Access Memory (RAM), 2 Gigabyte hard drive, an audio/video codec (coder/decoder) board, a video card with 1 Mbyte of memory to support an SVGA monitor with a resolution of 1024x768x8 bits. Communications supported include ISDN (single Basic Rate, BRI, to Primary Rate, PRI) through an integrated Inverse Multiplexor (IMUX) or T1 (1.5 Mbps) through the use of a T1 board and a CSU/DSU (Channel Service Unit/Data Service Unit). Ancillary equipment that can be added depending on each application includes remote stethoscope, dermascope and other medical scopes (otoscope, endoscope, etc.).

For clinical pharmacology, the motion video portion of this project will allow the consultant to discuss the case with the resident and examine the patient. A T1 line crossed over between the three rooms (Figure 2) is required. The lines are extended from the main T1 line within GUMC.

One need specific to clinical pharmacology is the ability to assess skin reactions to a specific drug therapy. For most clinical pharmacology applications, the physician located at the remote site will only need to look at the general appearance of the patient's skin such as observing the distribution of a skin rash and to characterize the skin reaction. Therefore, in those cases, the level of detail offered by commercially available dermascopes may not be necessary. A document camera (one chip CCD) is needed for review of the patients' EKGs, Pulmonary Function Tests (PFTs) and laboratory values.

Digital image data intensive applications are based on gray scale images and will have different requirements based on the modality, the clinical application and the primary operational setting (consultation or primary diagnosis). This type of data acquisition includes magnetic resonance imaging (MRI), computed tomography (CT) and radiology images obtained either through direct digital capture such as in computed radiography (CR) or through digitization techniques.

X-rays to be reviewed for Clinical Pharmacology are mainly chest x-rays. For diagnostic purposes, chest x-rays would require 2kx2.5kx12bits monitors. However, for this application, the system is used in a consultation mode.

Diagnostic audio intensive applications refer to applications where the diagnosis will be partly based on the audio component such as a remote stethoscope (clinical pharmacology) to monitor patient cardiac status. This places additional requirements in terms of bandwidth communications. Compressed audio may require anywhere from 64 to 128 Kbps of bandwidth. T1 capability is preferred because stripping away 128 Kbps from a 3-BRI line, leaving 256 Kbps, will deteriorate video image quality considerably. Currently codecs, which process and compress video and audio signals, handle a range of frequencies much smaller than the frequency spectrum of the human ear (50 to 7,000 Hz for codecs vs. 25 to 16,000 Hz for the human ear) (Turner, 1995). In our set up, stethoscope signals bypass the codec by using high quality audio encoders and decoders. The communication link between them is allocated separately on the T1 CSU/DSU.

5.0 Evaluation Methodology

Before establishing effectiveness of our telemedicine projects, we need to establish the technical efficacy of the system (NCRP, 1995). Does it perform reliably and deliver accurate information ? In other words, does it perform the way it is meant to perform: first in ideal conditions or lab setting then in routine clinical situations. In order to provide an answer to those questions and establish the necessary technical and performance requirements, several evaluation studies are being conducted for each clinical application. Once technical efficacy is established, the effectiveness of the system can be measured.

The main objective is to evaluate the impact of telemedicine on the medical decision making process for residency training. Using the GUMC Internal Medicine Resident continuity clinic as a pilot study site, a controlled comparison of telementoring (directing the resident from an off-site location to focus on rational therapeutic decision making for a given patient encounter) to on-site clinical pharmacology consultation has been developed. Evaluation of experimental and control groups is based on:

*Content (pre- and post objective testing) using Medical Knowledge Assessment Program for Clinical Pharmacology (MKSAP)

*Process (ability to identify pharmacotherapeutic issues in a standardized case and act on them)

*External blinded medical record audit

*Resident/Consultant satisfaction surveys

6.0 Optimal System Design

This project is designed for a six month period during which several designs and iteration will be tried. Based on the results of the technology assessment studies, the initial system designs are being modified in order to obtain the most appropriate performance for this clinical application. We anticipate that at the end of our studies, we will be able to establish the optimal system design requirements through testing and retesting of the different parameters.

7.0 Conclusion

Through the use of an integrated PC based platform, a telemedicine application is being undertaken with the Department of Medicine-Division of Clinical Pharmacology. Varying technical requirements are expected to support the different clinical applications. While there will be large areas of common requirements for many applications, each specialty application will have its unique requirements. We are developing several clinical protocols and evaluation methodologies to establish the technical parameters requirements through an iterative process. This will allow us to design and test the optimal design parameters for this clinical application.

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4.6 Telepathology Using the Internet

Primary Investigators

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Norio Azumi, MD

ABSTRACT

The International Consortium for Internet Telepathology (ICIT) project began to function this year using widely available non-proprietary hardware and software with the Internet as a method of communication. We have established a network for education and research in pathology among four international centers in three countries. The Imaging Science and Information Systems (ISIS) Center performs the roles of: 1) Network management; 2) Time coordination; and 3) File repository and maintenance for ICIT. We had telepathology conferences for about 23 cases this year. For our non-urgent telepathology cases, a high resolution (more than 1.5kx1.0k pixels) image is not necessary. As we have to consider Internet congestion from other Internet users, we should avoid using a very large image and taking longer time for a conference than is required. Although, even high compression, more than 1/10, 8 bit color or 128 colors, images are acceptable for our telepathology.

1.0 Introduction

ICIT project planning began in 1995; this year the ICIT project began to function using widely available non-proprietary hardware and software with the Internet. It is organized to establish an international telepathology network for education and research among four international centers in three countries. These centers are: Armed Forces Institute of Pathology (AFIP), in the USA; National Cancer Center (NCC), in Japan; Oxford University, in UK; and Georgetown University Medical Center (GUMC), in the USA. The ICIT takes advantage of the experience gained from cooperative studies between AFIP and NCC, and each of the four institutions' own experience with telemedicine.

The Imaging Science and Information Systems (ISIS) Center at Georgetown University performs the roles of: 1) Network management; 2) Time coordination; and 3) File repository and maintenance, for ICIT. From a network management and coordination perspective, our experience at the ISIS Center indicates that it is possible to establish quick and regular international pathology consultations focused on diagnostically challenging cases. We encountered two main limitations. The first was the relatively slow and occasionally unpredictable speed of communication over the Internet. The second was due to the time zone differences between the three countries. This time difference resulted in a fairly narrow window when normal operating hours of different international centers overlap making scheduling a video teleconference possible. By exchanging fewer carefully chosen diagnostic images, transmitted in a batch mode by the submitting pathologist prior to the live Internet video teleconference, it is possible to have shorter conferences with less intensive bandwidth demand. Our current goals are to: a) Further establish more effective platform-independent telepathology over the Internet; b) Determine the accuracy of telepathology consultation diagnosis, and; c) Evaluate its effectiveness in developing diagnostic consensus among experts.

2.0 Subject for Study

We focused our attention this year on the following three goals:

1. To research the effects of using the Internet for every participant,
2. To evaluate the method of image acquisition and the resolution for Internet telepathology,
3. To determine the procedures for teleconference and management of teleconference image evaluation.

3.0 Methods and Materials

3.1 Organization of ICIT

Each participating institution has a specialty.

1) Georgetown University Medical Center (GUMC) ISIS Center: Technical Issues and Management
2) Georgetown University Medical Center Department of Pathology: Lymphoma
3) Armed Forces Institute of Pathology (AFIP): Gastrointestinal and Uro-Pathology
4) National Cancer Center in Japan (NCC): Lung
5) Oxford University (John Radcliffe Hospital): Breast and Liver

ICIT system configuration is shown in Fig. 3.1.1.

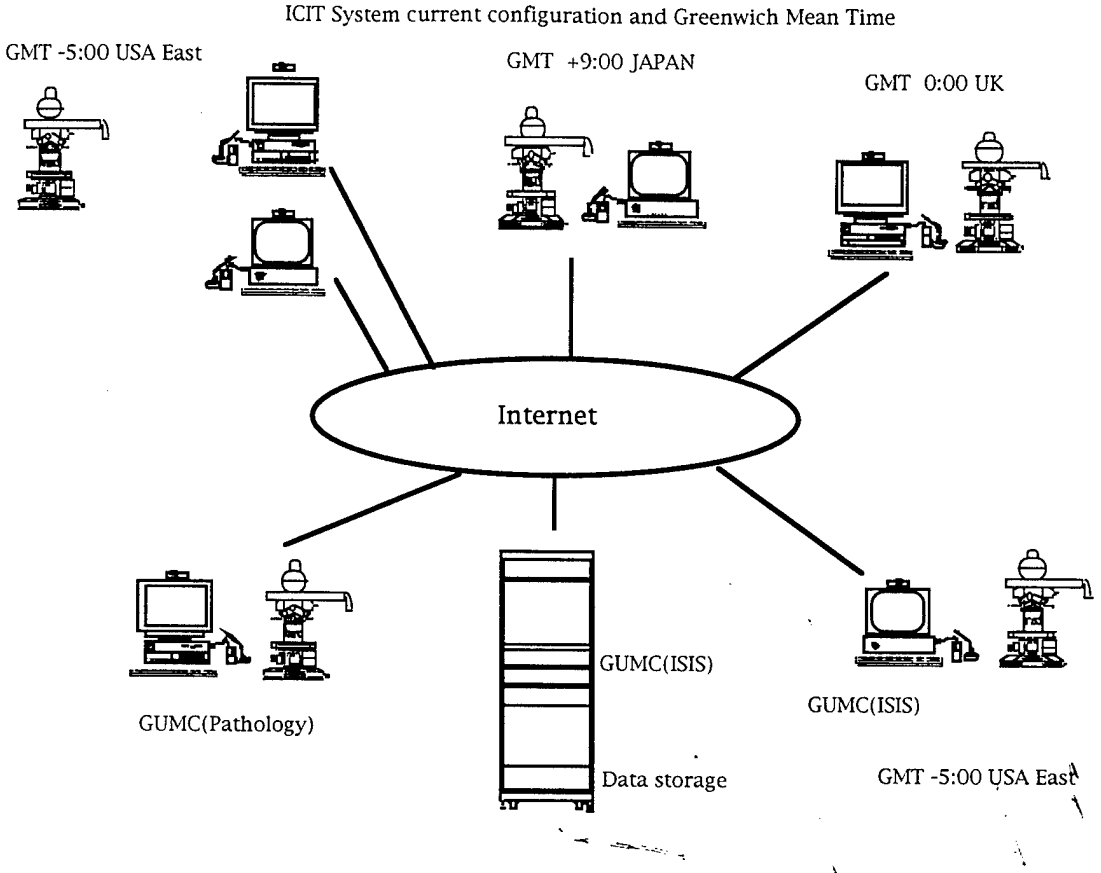


Fig. 3.1.1. System configuration.

3.1.2 System

As a non-proprietary system is used, only the minimum requirements are discussed below. In the beginning, we started to connect two systems *(Roche Image Manager and SGI InPerson)*. One institution has no SGI InPerson System, so in this case, *CUSeeMe* (free share) was used for TV conferencing.

Minimum requirements:

1) Workstation: e.g., SGI Indy2, IBM PC compatible, Macintosh
2) TV camera for capturing microscopic and macroscopic images
3) Internet connection

The Systems of Georgetown University

ISIS Center manages all data and network conditions for the project.

An Indigo2 (SGI) is used as a server for file transfer and network management. At Georgetown, the computers are required to have enough memory (at least 64MB) to be able to display several huge images (e.g., 20Mbytes/image) simultaneously in order to perform some of the trial studies for the project.

The description of the system for the Department of Pathology follows.

This is the system specification we recommend as a non-proprietary system.

PC Specification

OS: Windows 95, NT

*166MHz Intel Pentium Processor
* 512K Pipeline Burst SRAM cache
* 64MB EDO DRAM
* 3 ISA, 3PCI, 1 ISA/PCI Slot shared
* Phoenix Plug-n-Play Flash BIOS
* Intel 82430HX PCI chipset
* 1.44 MB 3.5" floppy disk drive
* 115ms 8X Eight Speed 1.2MB/S SCSI-2 CD ROM drive
* PCI 32-bit Ultra SCSI Fast-20 controller
* 9.0GB Fast SCSI-2 hard drive
* Diamond Stealth 3D 2000 Video Card w/2MB EDO & MPEG
* Creative Labs SoundBlaster 16 sound on board
* Advent AV007 computer speakers
* Adaptec AHA-2940U SCSI Host Adapter
* 1 parallel, 2 serial ports
* Tower Case
* 104 - key enhanced ps/2 keyboard
* Microsoft Mouse with Mouse Manager (ps/2)
* 3COM 3C509, ISA NIC Ethernet Combo
*#9 Imagine 128 8MB VRAM Video Card
* FCC class B, UL, CUL, & CE certified
* Iomega SCSI JAZ drive w/1.0GB removable cartridge
* Coreco Oculus TCX Video Framegrabber for RGB, NTSC, B&W, and Y/C Image Acquisition
* Motorola ISDN Modem HMTA 200
* 21" Superscan color monitor

Software

* Adobe PhotoShop 3.0
* WWW access software
* FTP software
* TV Conference software (CUSeeMe, Intel ProShare V2.0)

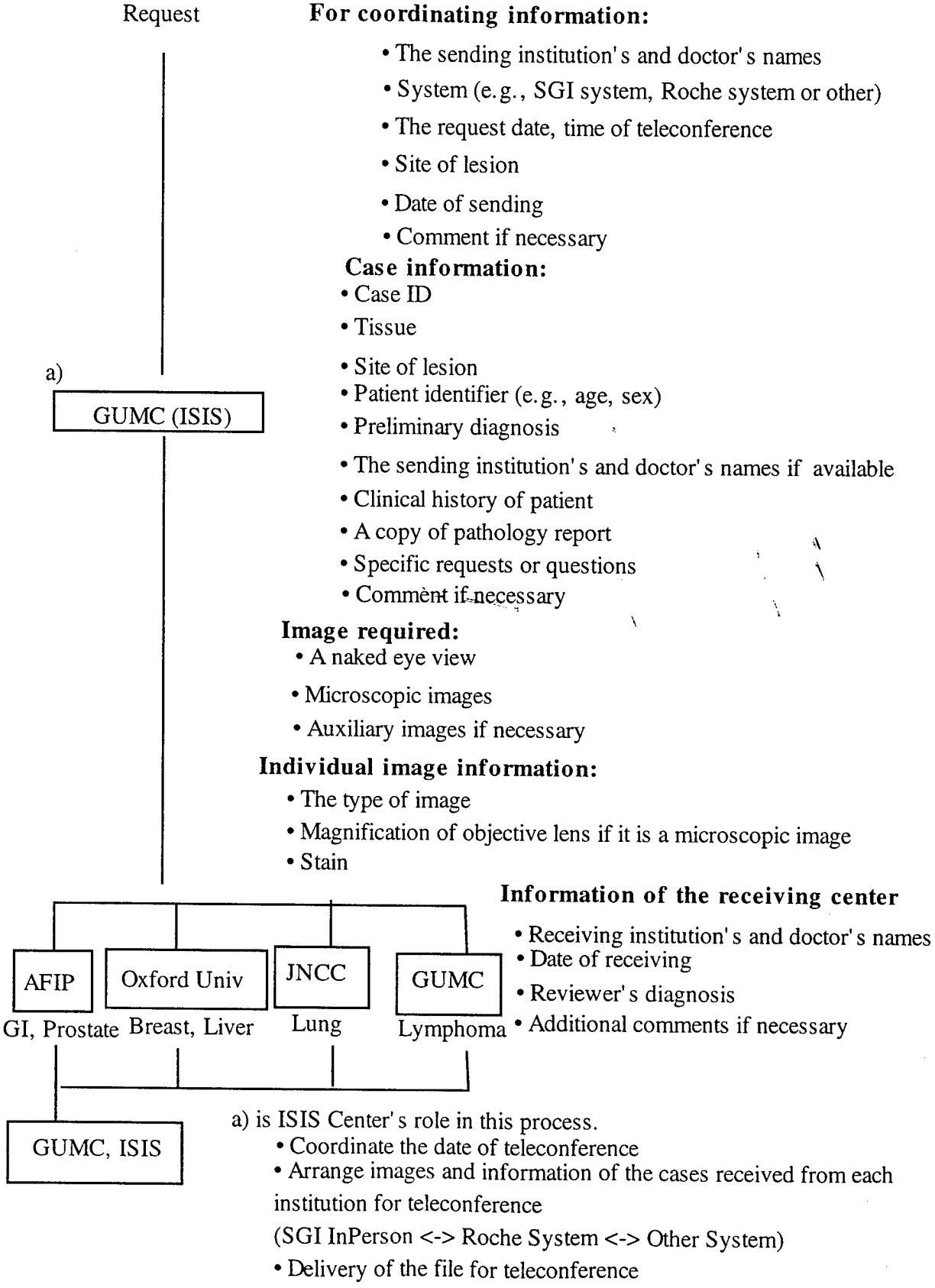
** Windows NT system has a Server software for FTP, WWW, and so on.

Image Capture, Output

* Sony DKC-5000 Cat's Eye Digital Camera
* Polaroid Sprintscan And Pathscan Enabler
* Connectix Computer Camera
* Kodak XLS 8600 Digital Printer

3.2 Operating Procedure for Teleconference

3.2.1. Preparing for Teleconference



3.2.2. Teleconference

- Ensure that the network and the system have no problems before conference.
- Basically, the time of discussion is about 15 minutes/case (depending on the case).
- After the conference, it is recommended to shut down each system to avoid network trouble.

3.2.3. Record Keeping

After the teleconference, the institutions make a final report. The sending institution, the receiving institution and the ISIS Center keep that file with those images.

3.3 Evaluation

To evaluate image quality, we used several kinds of resolutions:

1) Microscopic image
   a) 640x480 pixels
   b)1024x774
   c) 1536x1160
   d) 2048x1450
   e) 3072x2320
2) Image format
   a) non-compression (tiff, BMP)
   b) 1/5 JPEG compression
   c) 1/10 JPEG compression
   d)1 /30 JPEG compression

We compared 2 softwares for teleconferencing:
   a) CUSeeMe for Mac and PC
   b) InPerson for SGI

3.4 Time Coordination

The teleconferences would be held at the following times:

1) USA - UK USA : 7:30am - 1:30pm UK : 0:30pm - 6:30pm

2) USA - JPN

Standard Time

USA : 5:30pm

JPN : 7:30am

Day Light Time

USA : 7:30am

JPN : 8:30pm

3) UK - JPN

Standard Time

UK : 7:30am - 11:00am

JPN : 4:30pm - 8:00pm

Day Light Time

USA : 7:30am - 12:00am

JPN : 3:30pm - 8:00pm

4.0 Results

4.1 Network

The Internet communication condition among the 5 institutions is shown in Figure 4.1.1. From Figure 4.1.1., the network connection between NCC and Oxford is not good enough for TV conferencing through the Internet. While taking those data, we knew that the Internet communication capability around the Oxford area is not as stable compared with other connections. Between Japan and the USA it is becoming more stable compared with the same kind of data transmitted last year.

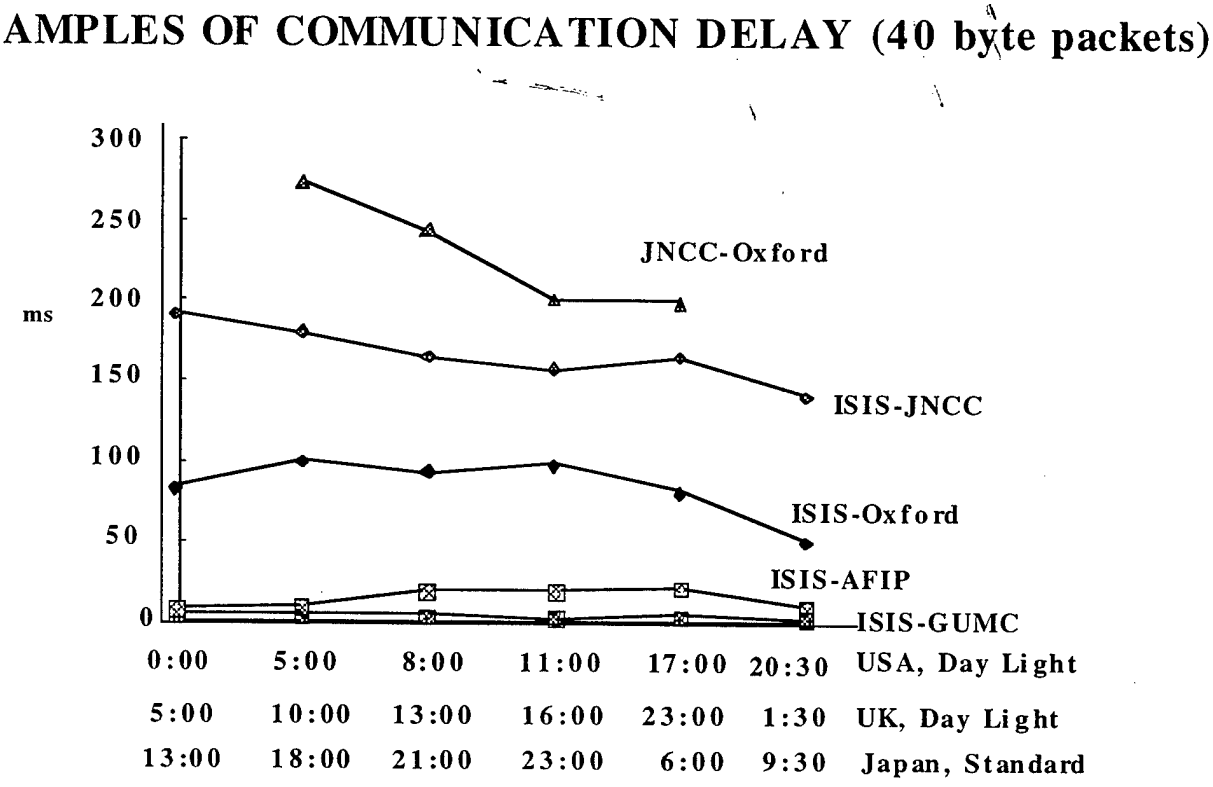


Figure 4.1.1. Internet condition.

4.2 Teleconference

Twenty-three teleconferences were held. Some the information is posted at the ISIS Center's World Wide Web site (http://www.imac.georgetown.edu/telepathology).

The time and number of images required for the teleconference is shown in Table 4.2.1.

Table 4.2.1 PREPARATION AND TIME REQUIRED FOR INTERNATIONAL INTERNET TELEPATHOLOGY SESSION

No. of cases	1 - 2 cases/session
No. of images required	5 -10 images/case
Time for preparation of a file	15 min/case
Time for preparation of a file to send back	15 min/case
Time for discussion	15 - 30 min/session

In reaching these data, we used an SGI system and 640x480 pixels resolution image. For higher resolution images, it took somewhat longer than indicated above.

The sample image on the monitor of teleconference is shown in Figure 4.2.1.

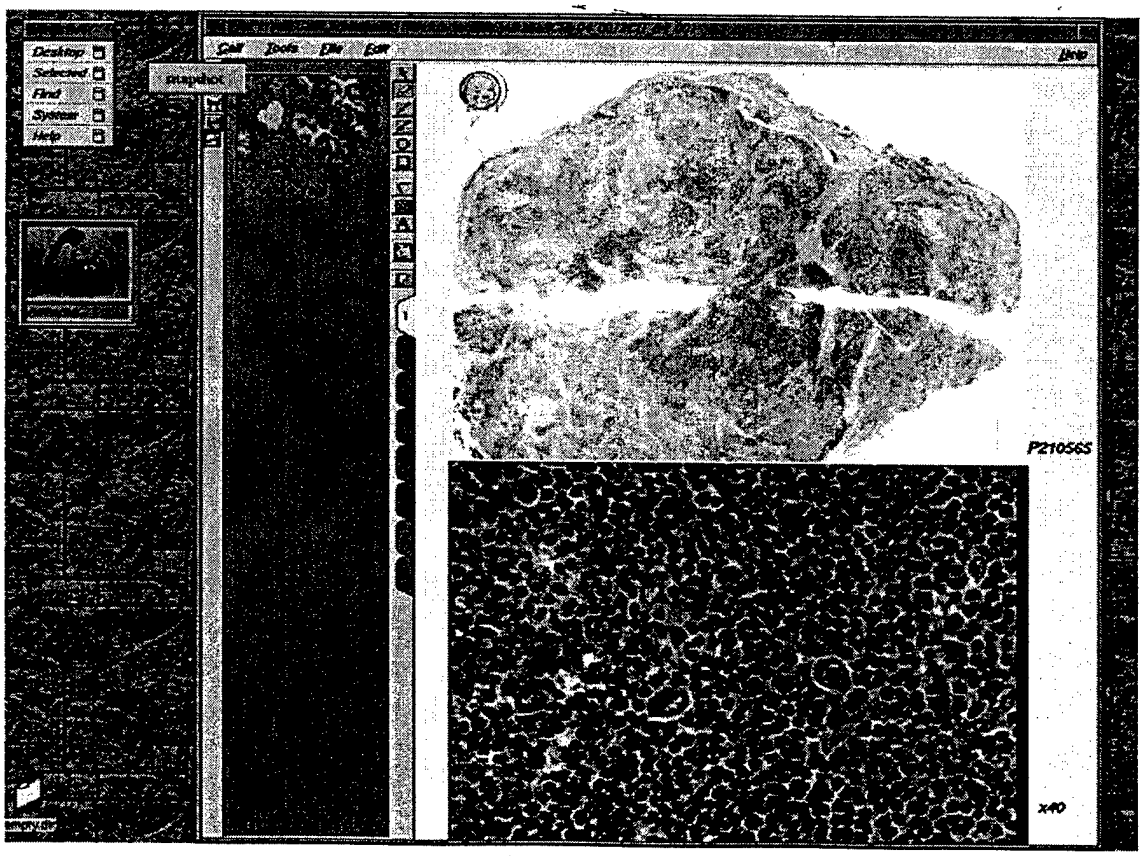


Figure 4.2.1.

5.0 Discussion

5.1. TV Conference Software

Though CUSeeMe is free share software, it has some inconvenient features such as not allowing for use of two-way voice transmission. When one person on one side speaks, they have to click a button to transmit their voice. The person on the other side cannot hear this person speaking.

On the other hand, InPerson (SGI) allows for smooth sessions. Inside the same country (such as in the USA between AFIP and GUMC) it is possible to use any software and use every function that software has. However, as our project is an international one, one must consider the limitation in TV conferencing.

5.2. Image

Usually, we used 640x480 pixels images, and sometimes 1024x774 for teleconferencing. For just 5 case images among the 23 cases this year, 1024x774 images were used. The remaining 18 cases images were 640x480.

We also used 3072x2320, 1536x1160, and 2048x1450. Most of our systems have 64 MB RAM, however, even then, we could not open enough images at once for one case. Capturing a good enough image using 2048x1450 3072x2320 was difficult, because the higher resolution image is apt to be influenced by such things as dust on the glass slide or the camera being slightly out of focus. Most of the pathologists felt that the image quality of 3072x2320, 1536x1160, and 2048x1450 images was excellent. This does not mean that they need these kinds of images for telepathology.

For compression, we used non-compression (tiff, BMP), 1/5 JPEG compression, 1/10 JPEG compression, and 1/30 JPEG compression. Most of the software's JPEG compression should be fine for telepathology. But some of the 1/30 JPEG compression images were clearly different from the non-compression images. Especially when using Adobe Photoshop v2.5.x.s for JPEG.

6.0 Conclusion

The exchange of opinions among pathology experts in various countries combined with their use of unified disease classification can yield tremendous scientific benefits. We are certain that telepathology can play a major role in realizing this goal.

7.0 Reference

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4.7 Digitization of Prostate Pathology Specimen

Primary Investigators

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ABSTRACT

The digitization of pathology data of the prostate is to assist in establishing a needle biopsy surgical simulation. We digitized 73 cases of whole prostates and stored all data onto CD-ROM, creating the Prostate Pathology Database. These data can be used for surface rendering and 3-D prostate reconstruction.

Through the primary study, the resolution of the digitization has been determined to be at 1500 dpi because it is the optimum resolution in relation to time for digitizing, size of image, needed space for storage and quantity of information. For instance, 200 MB/image is digitized by 5000 dpi, a 20 MB/image by 1500 dpi. Pathologists could segregate several regions well using 1500 dpi. The most important matter to get a good enough quality image is not the resolution of the digitization, it is the condition of the glass slide and proper usage of the system. Also, the conditions when the slides are made (i.e., if each slice is parallel to the next, if the slice has shrunk or not) influences the 3-D reconstruction quality.

This report includes just part of the pathology data digitization study of the whole process of the establishment of a needle biopsy simulation.

1.0 Introduction

In general, the size of prostate tumors are relatively small. In fact, prostate tumors are so small that despite the benefits of ultrasound, cancerous regions can go undetected. Current needle biopsies are thus performed blindly, and doctors cannot accurately pinpoint prostate cancer. In order to reduce the pain suffered by a patient during a needle biopsy, it is necessary to decrease the number of needles. To accomplish this goal, better interpretation of the ultrasound image and the corresponding histological data is necessary. Using this information along with MRI data, we can create the surgical simulation for needle biopsies.

Although the digitization of pathology data is only the first step towards the establishment of needle biopsy simulation for the prostate, the data contains both basic and original data, the quality of which is retained, and the quantity recorded. Without the retention of data quality and quantity, correct results would be difficult, if not impossible, to obtain.

To determine the property resolution for digitization, it is necessary to consider the following.

1.1 Analysis of 3-D Features

Once the three-dimensional model is constructed, several questions need to be answered. Although the surface rendering helps us to visualize the prostate, the analysis of the 3-D model should provide the answers to the following measurements:

1. The likelihood of adequate tumor sampling according to various biopsy methods (e.g., the simulation application for needle biopsy).
2. The enumeration and spatial distribution of tumor foci (including measurements of symmetry in that distribution).
3. Measurements of total tumor volume, and tumor volume as a fraction of total prostate volume.
4. Volume and distribution of extrapostatic tumor.
5. Distribution of surgical margins with prostate glands at the margin. Such margins represent areas of presumptive incomplete prostate excision.
6. Correlation of the distributions of prostatic intra-epithelial neoplasia and invasive tumors.

*Ultimately, the effect of clinical features on the measurements described above will be studied. A few of these features are in the clinical stage (e.g., anti-androgen therapy and perineal vs. retropubic resection).

2.0 Materials and Methods

The resolution of the digitization has been determined to be at 1500 dots per inch (dpi). Materials: 73 cases (containing registration marks for reconstruction). Each prostate case consists of 13 to 20 slides containing slices 2.25 mm apart.
The system requirements to digitize the pathological specimens are:

-Power Macintosh
-Adobe Photoshop 2.5.1 or later version
-Leafscan 45 Scanner
-CD-ROM Writer

Note that each image required approximately 17 MB - 20 MB of uncompressed disk space, so several Bernoulli disks / FTP capabilities are advisable.

The slides are to be prepared by slicing the resected whole prostate. Each slice should be parallel to the next. Once these slides are digitized, we can stack the images on the z-axis in order to construct a three-dimensional model.

Previous research has been done using low resolution digitization (i.e., 75-100 dpi). However, in microscopic image research, the images are not clear enough to pinpoint tumors. Characteristics of the cancerous tumors are also hidden in the blurred images.

In our study, we adopted a high resolution digitization at 1500 dpi. The method we follow is outlined below:

1) Each resected prostate consisted of approximately 11-20 slices. The distance between adjacent slices is 2.25 millimeters.
2) The primary data was taken by digitizing prostate specimens at the pre-established resolution (1500 dpi) using the *Leafscan 45* Scanner.
3) After digitization is complete, the pathologists isolate and mark the location of each tumor. The pathologists segregated several regions (seminal vesicles, urethra, registration marks) in each slice, and marked their respective "paths" using *Adobe Photoshop 3.0*. We attempted to extract these "paths" from *Adobe Photoshop 3.0*, and use the information to align each slice with the next. These marked "paths" aid in the surface rendering and 3-D prostate reconstruction.
4) Using the data collected, we stacked the slices on top of one another in order to construct the three-dimensional model (both surface rendering and volume rendering). Because the slices are 2.25 mm apart, there is a problem in connecting the spaces between them. Once the slices are aligned on top of one another,

however, connectivity of contours between consecutive sections is assumed if and only if the contours overlap.
5) Using CD-ROM writer, all case data were saved onto CD-ROM as our database.

These data were saved by TIFF format and are readable by *Adobe Photoshop* version *2.5.1* or later.

3.0 Results

Digitizing by 1500 dpi, the time for working and size of data is shown in below.
1) Numbers of cases: 73
2) Data size: 17-20 MB/image
200 - 300 MB/case
3) Time for digitization: 1.5-2 hour/case
: 5 cases/day (max.)
4)Time for segregation: 2 hour/case (min.)
5) Time for writing CD-ROM: 1.5-2 hour/case
: 5 cases/day (max.)

4.0 Discussion

4.1 Quality Assurance

In order to collect the most reliable data possible, we knew that we must follow a quality assurance procedure. It must strictly follow the steps listed above for prostate slide digitization. Several more important steps are listed below:

1. Each slide must be cleaned before digitization using isopropanol glass cleaning solution or ethanol. If any dust marks are left on the slide, they will interfere with the total quality of the digitized image.
2. The prostate slide must be wiped carefully in order to retain the registration dots. This can easily be done using Q-tips and 95% EtOH solution.
3. The prostate slides must be placed on the film holder with the label facing up. The label must not extend into the 6x6 cm square, as it will also interfere with the image's color.
4. Once the slides are placed in the inner pocket of the film holder, the white hash mark must line up with the "0 degree" mark on the outer pocket. This ensures that the image will appear upright on the screen.
5. The Leafscan 45 scanner must be recalibrated at the beginning of each digitizing session.
6. The last slide of each prostate case is flipped over. This is done because each prostate was cut manually for the last slice. The digitizer should flip the last slide keeping the white label on the top of the slide.
7. In order to keep the resolution at 1500 dpi, the width and height of the black lines must be locked and unlocked according to the instructions above.

4.2 Questions for Future Study

In our study, certain difficulties arose because of time constraints and technological restrictions. These are listed as follows:

1. Digitizing the images:
a. Once the image has been prescanned, the digitizer must minimize the blue box and relocate it to the area of "greatest color contrast". However, it is sometimes difficult to locate this spot on the image.

b. The color of each image should theoretically be the same. However, using the Leafscan 45 scanner and Adobe Photoshop 2.5.1, the digitizer can only approximate the color of the image to be the same.

c. Another problem that arises once the image has been prescanned is the focusing. Since the Leafscan 45 scanner is designed to scan film, not glass slides, the focus is not always perfect.

2. Creating the three-dimensional model

a. The problem in creating the 3-D model is that each slice is 2.25 millimeters away from the next one. This makes it difficult to construct the contours of the prostate in each 2.25 millimeter gap.

b. We dealt with resected whole prostate. Some tumors expand outside the prostate in the human body. From examining only the prostate, actual tumor size cannot always accurately be determined.

5.0 Conclusion

In digital pathology, the quality of most pathology images, such as microscopic or macroscopic, correlate to material conditions. Sometimes, we would need to remake a specimen if the original had any problem. As an original resection normally has been kept at the institution for a long time, a number of defects due to dust and mishandling may result. The original resection and other data are helpful to know when tackling a problem such as in section 4.2, 2a.

For these data, CD-ROM is useful as a database because they are so large, more than 200 Mbytes, and any kind of computer should be able to read CD-ROM data.
We are going to make a more useful database with added microscopic image and case and patient information.

4.8 Telemedicine Multimedia Database (MM-DB)

Primary Investigators

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Walid Tohme, PhD

1.0 Introduction

The aim of this project is to develop a prototype multimedia database (MM-DB) for telemedicine applications. Telemedicine applications have been flourishing around the world but the technical requirements and specifications are still under development. Telemedicine is likely to increase access of patients to care, improve the level and quality of the care they are receiving and most of all reduce its cost. Telemedicine encompasses voice, video in addition to digital images, and data. Therefore the importance and complexity of creating a multimedia database for telemedicine become obvious. MM-DB concepts apply to several clinical environments since it includes the storage, retrieval and access to digital images, diagnostic audio and video and still color images.

In order to ensure a high level of success, we have decided to develop a prototype modeled after a MM-DB for nephrology applications first. Nephrology is one of the clinical applications that lend itself the most to Multimedia Databases. This stems from an existing need in nephrology to remotely monitor patients from separate sites where the physician is located. There are several reasons for this among which:

* The need exist in nephrology to monitor patients over long periods of time for longitudinal type studies.
* Retrieving, storing and accessing patient history and laboratory values in patient folder format is essential
* Data stored includes diagnostic audio, diagnostic video, still color video, still digital images and data.
* Amount of information to be handled/ retrieved and accessed is large as patients come in for dialysis three times a week and data is stored on a regular basis (see operational description).

The overall object of this project is to be able to apply this MM-DB to other clinical applications. The ISIS Center at Georgetown University Medical Center (GUMC) is undertaking several telemedicine projects with various departments within the medical center. These projects include:

* Patient Monitoring: Telemedicine with the Department of Internal Medicine- Division of Nephrology
* Distance Teaching: Telementoring with the Department of Medicine- Clinical Pharmacology Division
* Surgical Urological Stone Evaluation: Multimedia teleradiology with the Department of Surgery
* Pediatric Trauma Triage: Telemedicine with the Department of Pediatrics-Division of Critical Care
* Battlefield Trauma Simulation: Telemedicine with the Department of Veterinary Medicine and the Department of Surgery.

2.0 Structure of the Paper

This paper first describes (in Section 3.0) the clinical assessment scenario around which this project is built. In Section 4.0, the operational setting is then described along with the storage requirements for each type of data (diagnostic audio, still video, diagnostic motion video, still image, data capture from the central server and from patient charts). In Section 5.0, the MM-DB to be developed is described in terms of its browsing capability, multi-level indexing and ability to handle queries with different levels of complexity. Finally, in Section 6.0, we describe the research plan which we intend to follow.

3.0 Clinical Assessment Scenario

Patients are brought in for regular dialysis treatment approximately three times a week. The clinical assessment includes :
1) Cardiac status and pulmonary fluid state evaluation. This is done through an electronic stethoscope.
2) Laboratory values (to include EKGs) mainly through patient charts.
3) Evaluation of shunt through visual assessment as well as vascular ultrasound evaluation every three months to establish any shunt stenosis or narrowing.
4) Patient/physician interaction

4.0 Operational Scenario and Storage Requirement for Nephrology Application

Patient is evaluated through video, remote auscultation and data transmission. The database will be located at the patient's site and it will be accessible from the physician's remote site.

4.1 Diagnostic Audio Requirements (Cardiac/Pulmonary Status)

Once a week, for routine cases, a portion of the auscultatory findings for cardiac and pulmonary assessment is recorded and stored into the patient folder. Through the electronic stethoscope, the signal is sampled at 44-48 KHz and 16 bits of dynamic range. The transmission rate required to transmit such a signal is around 128 Kbps.

Frequency : Once/week/patient (routine cases)
Source: electronic stethoscope
Sampling rate: 16 bit, 44-48 KHz
Transmission Rate: 128 Kbps

Cardiac Assessment:
Location: Heart
Length: 15 seconds

Pulmonary:
Location: Lungs (right and left)
Length: 10 seconds (total 20 seconds)

Estimated storage requirements: 128 Kbps x 35 sec / 8 = .56 MBytes/patient/week

4.2 Still Video Requirements: (Evaluation of Shunt)

Still video capture will be used for shunt evaluation. This will also be done with vascular ultrasound. The shunt still video will be captured once a week per patient and will be done and stored on the patient side.

Frequency: once/week/patient
Resolution: 640 x 480 x 24 bit color
Source: Video camera
Estimated Storage Requirements: .92 MBytes/patient/week

4.3 Motion Video: (Shunt Evaluation)

Motion video will be used for video conferencing purposes including patient to physician interaction and dialogue. Mostly it will be used as a diagnostic tool for the evaluation of the shunt. This will be evaluated through vascular ultrasound. This needs to be done about once every one to three months for about 30 seconds. If images are frame grabbed then it will be the same as still video in terms of requirements.

Real-time ultrasound
Resolution: 640 x 480 x 24 bit color x 30fps = 221 Mbps
Source: Vascular ultrasound
Frequency: 1/month
Duration: 30 seconds
Estimated Storage Requirements: 830 MByte/patient/month

4.4 Data Capture

Computerized dialysis machines are capable of downloading data to a central computer in order to observe changes in sodium, blood pressure, temperature, etc.. Data can be stored, acted upon if machine alarms are triggered, and adjusted by the physician prescribing the dialysis procedure. Other data is usually needed to assess patient history such as laboratory values and patients charts.

4.4.1 From Central Server Screen:

Data will be captured from the central server through an interface with the telemedicine workstation. Data captured from central server screen needs to be done three times during each patient session at each of the three times that the patient is scheduled for dialysis. The data capture is done once five minutes into the dialysis, at the mid point and then again once five minutes before the end.

Frequency: 3 times/patient/session/@3 sessions/week = 9 times/patient/week
Type: Patient information: Blood pressure, oxygen saturation levels, etc..
Source: Video camera
Resolution: 320 x 240 x 8 bits
Estimated Storage Requirement: .7 MByte/patient/week

4.4.2 From patient charts:

Information from patient charts will be captured through a document camera. This will be freeze framed and sent as compressed JPEG file.
Source: Document camera
Type:: EKG, lab values = 5 pages
Resolution: 320 x 240 x 8 bit
Frequency: once / month
Estimated storage requirements: .384 MByte/patient/month

5.0 Database Requirements

Our database will be a multimedia telemedicine database that will be able to handle full motion diagnostic video, still video, diagnostic audio as well as still gray scale images. It will be based on concomitant metadata as well as derived metadata and will be able to perform:

* Browsing of all data types
* Multi level indexing including visual indexing

* Processing queries of different levels of complexity

5.1 Browsing of all data types

The Nephrology MM-DB will contain full motion video, still video (24 bit color), gray level image, sound and text data. One of the features of the system will be to provide an efficient way to browse this database. Since the video and image data require the most storage, and also have the higher retrieval times, these two data types will be the focus of our initial design. For browsing of images we will use an approach based on wavelets, and for video we will use a combination of wavelets and shot segmentation algorithms.

5.2. Multilevel indexing, including visual index

Indexing of a multimedia database is a key component of accessing the data elements. Further, since each access to a data element may require the movement of large amounts of data - typically an image, video sequence or sound track - the indexing scheme must be such that incorrect accesses are minimized. The indexing of MM-DB will be based on the concomitant data collected at the time of data capture, and on the bases of derived indices. The latter indices will be based on the content of the multimedia data element.

5.3. Processing queries of different levels of complexity

The type of queries to be included in the system is dependent on the physician requirements. To begin with we will ensure that all the selection type of queries will be available to the user. Next we will build in all other relational (SQL based) queries. These queries have to be dependent on the text fields, i.e. the patient and sensor information, the concomitant indices, and the derived indices. The outline of our approach to these is described in a paper (included as an Appendix). The next key step has to be an understanding of the protocol that is used by the physicians. On the basis of this study we would develop an understanding of the primitives that would be required, and include this information in developing a query formulation approach. For example, we will determine the functionality is critical when the style of operations change to that using telemedicine with MM-DB.

6.0 Research Plan

1. Interview physicians, specialists and other designated personnel. Assess the information that is useful in their decision making. What is the role of historical patient information. Develop a rank order of the importance of each information item.

2. Develop performance metrics for evaluation of the multimedia database usefulness.

3. Collect sample data for some patients.

4. Collect concomitant metadata to describe the data collected about the patients.

5. Develop algorithms for automatic extraction of the derived indices. We will use the wavelets approach described in our paper as the starting point of this analysis.

6. Choose the browse images most appropriate for the important functions to be performed by physicians.

7. Use the data set collected to validate the browse approach.

8. Assess the effectiveness of the indexing approach, by determining precision and recall characteristics, and the effectiveness of the approach to focus the search.

9. Evaluate the performance of the system.

10. Perform scalability analysis with respect to the volume of data in the database, the computing capability available, the communications capability, the number of users, and the application environment.

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Chapter 5

Patient Confidentiality and Data Security

5.1 Approach to Safeguarding the Confidentiality of Patient Records

Primary Investigators

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ABSTRACT

This paper demonstrates a general approach for protecting the security and confidentiality of patient records in health applications of the National Information Infrastructure (NII). We are investigating two hypotheses. We aim to show that electronic telemedicine systems, when managed according to established information security practices, provide increased access to and maintain the security of patient information, compared to paper-based medical records. We will also examine whether, when properly informed about the institution's policies, procedures and methods for maintaining the confidentiality of their medical records, patients will agree to using telemedicine systems and to storing their information in an electronic medical record.

1.0 Introduction

The Renal Dialysis Patient Management illustrates security and confidentiality issues in health applications in the range of networks from point-to-point T-1 and ISDN lines, satellite communications and the Internet. This paper defines a general approach for protecting the security and confidentiality of patient records in health applications of the National Information Infrastructure (NII).

Two hypotheses will guide the work. Hypothesis One focuses on institutional policies, practices and technological methods for managing information security. Hypothesis Two focuses on patient understanding of institutional practices and consent to including their health information in an organization's information management system.

2.0 Hypotheses to be tested

2.1 Hypothesis One

Hypothesis: Electronic telemedicine systems, when managed according to established information security practices, provide increased access to and maintain the security of patient information, compared to paper-based medical records.

Aim 1: Perform security risk analyses and implement risk management plans for the electronic and paper-based versions of the RDPM network using access, authentication and encryption tools;

Aim 2: Develop and compare usability-security curves of the electronic and paper-based Renal Dialysis Patient Management systems, and;

Aim 3: Review, implement and evaluate the impact of access, authentication and encryption tools for enhancing security of DICOM based communications on the Internet.

When the evaluation of this hypothesis is complete, a better understanding will exist of the tradeoffs between usability and security for electronic and paper-based record management systems in health care applications of the NII.

Rationale and Related Work to Hypothesis One

In its recently published study of the contemporary patient record, the Institute of Medicine identified five conditions that favor and virtually make inevitable the computerized medical record (CPR)[1]:

1. the uses of and legitimate demands for patient data are growing in clinical care, financial and organizational administration, clinical research and medical practice guideline development;

2. more powerful, affordable technologies to support computer-based patient records are becoming increasingly available;

3. computers are increasingly being accepted as tools for enhancing efficiency in all facets of everyday life;

4. the aging and mobility of the US population create pressures for easily transferable patient record systems that can manage large amounts of data, and;

5. the automation of patient records is crucial to successfully reforming the health care system.

The very success of this process and its perceived inevitability nonetheless have provoked broad professional and public concern about its effect on patient privacy and the confidentiality of their records[2,3,4,5]. Particular concern exists about the vulnerability to hostile attack and abuse of computerized patient records connected to local and wide area networks, including telemedicine networks.[6] Insofar as telemedicine systems perform as they are being designed to perform, their ease, wide distribution and speed of communication will potentially give more people greater access to patient medical records. How can the managers of telemedicine systems provide the benefits of increased access while safeguarding system security and the confidentiality of patient information?

Traditional methods of protecting confidential patient information primarily relied upon the moral constraints of the doctor-patient relationship, namely the doctor's integrity and subscription to the canon of medical ethics as embodied in codes such as the Hippocratic Oath and the circumscribed demand for the information The general conditions of contemporary health care, particularly in the type of tertiary care institutions likely to implement full-scale telemedicine and CPR systems, transcend the boundaries of this traditional model and make difficult protecting the confidentiality of patient records [4,7,8,9]. These conditions include:

1. many types of people (physicians, nurses, receptionists, billing clerks, clinical researchers, administrators, insurance company functionaries and others) have legitimate access to patient medical records;

2. many legitimate uses (direct patient care, quality assurance, medical training, clinical research, billing, regulatory review and others) now exist for patient data;

3. patient data is routinely transmitted outside the boundaries of the health care setting in which it was originally produced (hospital corridors, clinical and teaching conferences, scientific presentations, health insurance companies, central data collection companies, commercial clients of central data collection companies), and;

4. third parties with non-health care related interests and no constraints based on the medical tradition of confidentiality (for example, risk rating in employment, life insurance, and credit) have access to patient medical information.

Noting the negative impact of these types of conditions on patient confidentiality, Woodward asserts, "But computerized records, particularly if embedded in large networks designed to collect comprehensive life-long data, can rapidly accelerate that trend [in the deterioration of confidentiality]".[6] Woodward cites examples of spectacular abuse of patient medical data as evidence for the inevitability of this process.

Woodward's concern may be expressed in terms of a utility curve portraying security and access as inversely related. As Amoroso states, "a conflict generally occurs when the goal of information and resource sharing is combined with the goal of strict security between users".[10] When usability (in this case, access to patient records) increases, security decreases. When security (defined as prevention of information disclosure, protection of data integrity, and assurance of adequate service) increases, usability decreases. Amoroso illustrates this trade-off between usability and security with the following diagram:

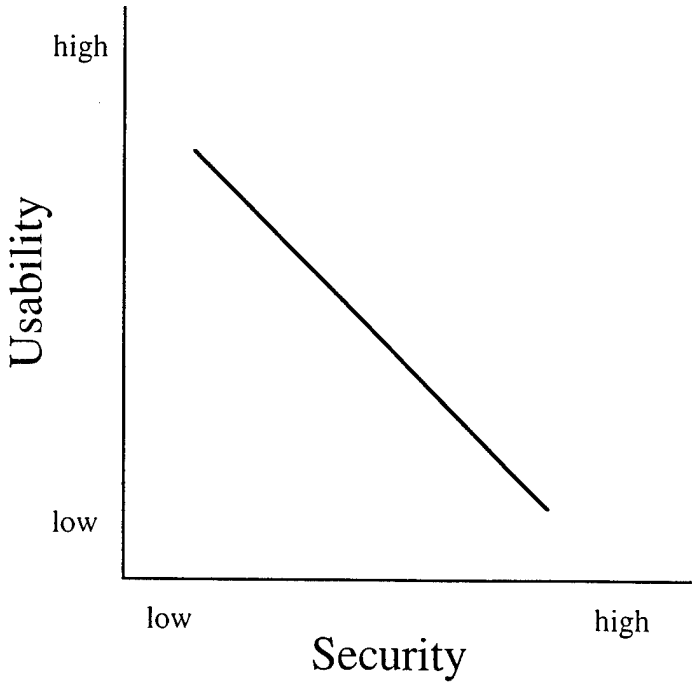

DIAGRAM A

This formulation of the problem, however, assumes the potential existence of only one usability-security curve. Within the context of any given technology and set of security management practices, only one curve plotting the range of solutions may be possible. Changes in technology (for example, the change from paper-based to computerized patient records) may change the equation relating usability and security, change the range of possible solutions to the equation and thereby define new, different curves. Changes in security management practices (for example, a change from a pattern of infrequent to frequent auditing of system use) may similarly create a different curve for a particular records management technology. The following diagram illustrates these possibilities.

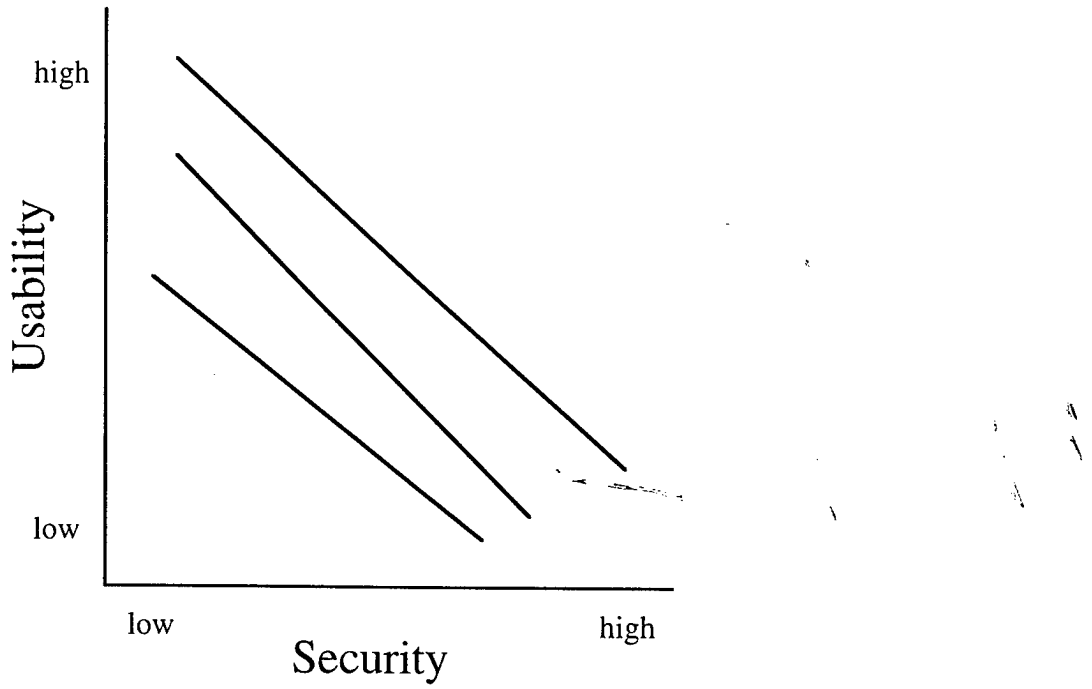

DIAGRAM B

A simple example plotting the number of users capable of simultaneously using a record (a measure of access) against the use of auditing to track system use (a measure of security) will illustrate this point. Accessibility may be rated according to the number of people who may simultaneously consult a record from one to some upper bound, say four. The greater the number of people who may simultaneously use a record, the more accessible it is. Security systems may be rated according to the use of auditing methods either used or not used. Systems that exploit auditing technology (paper-based or electronic) are more secure than systems that do not use auditing. A set of four parallel curves is defined for the set of systems that provide access from one to four simultaneous users and that may or may not use auditing technology (see Diagram C).

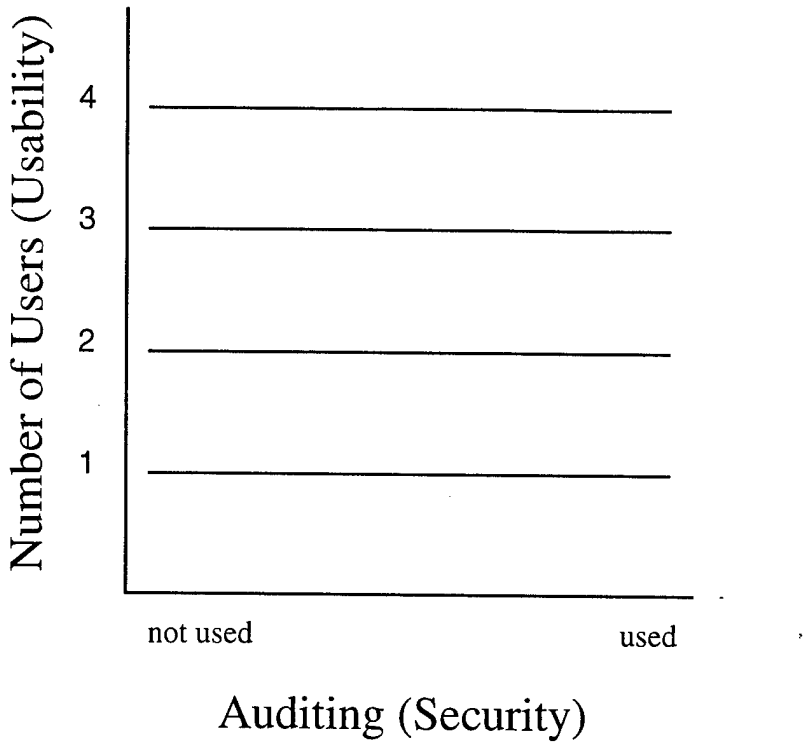

DIAGRAM C

The potential existence of a series of usability-security curves requires a reformulation of concerns about the comparative security of computerized and paper-based patient records. Traditional paper-based systems provide access to a patient record to one user at a time, such as a patient or physician. Unless copies are made, a record exists in only one location, making it potentially inaccessible and vulnerable to changes, damage and loss. The physical uniqueness of paper-based patient records may make it easier to track records, to prevent unauthorized disclosure of confidential information and minimize the quantity of disclosed information. Electronic patient records can be accessed simultaneously by many different users in separate locations, thus increasing access and availability. Because they can be examined and modified from several locations at once and because electronic patient records can be easily transferred through telecommunications media, they may be more susceptible to unauthorized disclosure and modification. Sophisticated computer security systems have been developed by the field of information science, that stratify access, create audit trails on data changes and system use, safeguard patient data from corruption, and protect databases from outside invasion.[1,11,12,13,14] These new tools potentially provide a different level of security for any given level of access, generate a different set of tradeoffs between usability and security, and define different usability-security curves than the paper record.

While security tools exist for both the paper-based and the computerized patient record, they must be applied to have any impact. The issue is organizational as well as technological. As with paper records, one must actively manage the computerized patient record and apply the new tools according to established principles of information management. Variations in management practice affect the level of security achieved with any given security technology, with less rigorous practices diminishing its functional capabilities. Spectacular abuses are most likely to occur when management is indifferent, whether information is stored in an electronic or a paper-based medium. Within the context

of any given technology, one will therefore find a band of usability-security curves defined by the range of management practices used in its implementation.

The potential existence of more than one usability-security curve complicates hospital administrators' choices about information security management strategies. Within the context of a given system of technology and set of management practices, hospital administrators must weigh the need for utility and access against the need for system security. Administrators may decide to make their information management system quite secure at the expense of minimizing access. Or, they may make it more accessible at the expense of security. The development of computerized patient record management systems makes available more than one range of utility-security tradeoffs. Administrators must choose between usability-security curves as well as a place along the range of any particular curve. Given that a primary reason for adopting electronic information systems particularly in health care is to increase access to patient information of authorized users, administrators may make some sacrifices in security with the computerized patient record. However, they already make sacrifices with the paper-based record. The paper-based record is not a risk free "gold standard" against which unambiguously to measure the electronic record. The issues are what kinds of risks a particular health care organization is willing to manage, at what level of effort and for what costs, not whether it will manage risks to its information system. When evaluating the security of an electronic patient record, health care administrators must ask such questions of both the electronic and the paper-based systems and relate the answers to their organization's strategic plan.

What are the elements of good information security practice? Richard Baker has outlined an approach to developing sound information security practices based on the idea that information is an organizational asset as well worth protecting as any other piece of real property.[15] Protecting this asset, however, requires that one must first assess potential threats to the information and then develop a plan to control the threats. In light of the great concern about the potential for malicious, outside attacks on a computerized patient record over a network, Baker makes an interesting point: the vast majority of security breaches are inadvertent and made by insiders. Insiders also make most malicious attacks. Outside, malicious attacks compose a small if nonetheless highly publicized minority of security breaches. The greatest barrier to developing effective protection against all breaches is management indifference, not the lack of technology. When management commits organizational resources to assessing and controlling network security risks, the first element of good information security practice has been met.

The foundation of good information security is an ongoing process of risk analysis (see Approach). A risk analysis includes a detailed assessment of an information systems' vulnerabilities, a calculation of an institution's expected loss in the event an identified breach actually occurs, plans for addressing each identified vulnerability, and an estimate of the cost of implementing the risk management plan. One should examine all aspects of an information system, including its physical, administrative, staffing and technical characteristics. As risk management plans are developed, implemented, and evaluated, risk analyses should be repeated to assess the effectiveness of past work and identify new, emergent risks. It should be noted that although a risk analysis may identify certain technical work that must be done, managing information security risks is fundamentally an administrative process.

Health applications of the NII have raised special concerns because sensitive patient and organizational information will regularly travel over and be accessible from the Internet, making it vulnerable to interception, modification, computer break-ins, and denial of service attacks. Various tools are available to help control such threats in commercial

organizations.[16] The ongoing development of the DICOM standard for medical image communication provides special opportunities for building security tools into an evolving standard affecting the design of medical equipment. Access, authentication and encryption tools exist that may be applied in network protocol layers supporting the transfer of medical images. These tools include the Secure Sockets Layer, for example, which is now used for many World Wide Web applications.[17] Project Phoenix will conduct a formal evaluation of existing tools, comparing their relative utility and cost in enhancing the security of medical communications over the Internet. The results of this work will be forwarded to DICOM standards organizations for evaluation of their potential relevance to future standard revisions.

2.2 Hypothesis Two

Hypothesis: When properly informed about the institution's policies, procedures and methods for maintaining the confidentiality of their medical records, patients will agree to using telemedicine systems and to storing their information in an electronic medical record.

Aim 1: Develop patient educational materials in video, written and oral formats explaining the testbed's policies, procedures and methods for maintaining the confidentiality of medical records in the electronic and paper-based systems;

Aim 2: Include the educational material developed in Aim 1 as part of the process for obtaining consent of a test sample of patients to participate in the electronic RDPM network and request consent to use the telemedicine and computerized patient record systems to manage their information, and;

Aim 3: Obtain explanations for patients' consent or refusal to have their information managed by the electronic RDPM network.

When evaluation of this hypothesis is complete, a better understanding will exist of the extent to which patients' concerns about the confidentiality of their medical information are important barriers to the development and deployment of telemedicine.

Rationale and Related Work to Hypothesis Two

When patients provide health care workers with information about themselves, they routinely expect that the information will remain confidential and that their informed consent will be sought when it is necessary to give information to a third party.[15] Most hospitals require patients to sign various types of authorization and consent forms upon presentation for care, including general consent for care forms, special procedure informed consent forms, clinical research consent forms and third party payer assignment forms. Questions still remain, however, about how much patients really know about the use and distribution of the information they surrender. One might suspect that many patients are unaware of the number, types or purposes of people who will legitimately review their records. How many patients know how their information is stored? Even when patients sign third party payer assignment forms, do they really understand who outside the hospital may eventually have access to their information with patient identifiers? For example, how many patients appreciate that health insurance companies send patient information to central data banks who may resell it to yet another party? These questions raise serious issues about the legitimate uses of patient information in a paper-based system to say nothing about the opportunities for illegitimate and abusive violations of patient confidentiality in an electronic system. The possibility exists that when patients provide health care institutions

with information about themselves, they are not really doing so under conditions of informed consent. This point is quite pertinent to patients' acceptance of telemedicine and the CPR.

Equifax Inc. in conjunction with Louis Harris & Associates and Alan F. Westin has been conducting an annual consumer privacy survey since 1990. In 1995, it released the Equifax-Harris Mid-Decade Consumer Privacy,Survey summarizing results of its latest survey and comparing them with trends from earlier years.[18] A special section was devoted to assessing the public's attitude toward the computerization of the patient record. The news for telemedicine and the CPR is good. A majority of people surveyed see the trend toward the CPR as beneficial and important to them, but they expressed concern about potential negative effects. Their concern about potential negative effects abated, however, when informed about some organizations' development of codes and practices to safeguard the confidentiality of electronic patient records. These practices include informing patients how their records are used, setting rules of confidentiality, making it possible for patients to see their medical record, keeping medical records separate from other consumer databases and ensuring that medical records are not used for marketing products to consumers. Instituting a comprehensive process of informed consent about an organization's policies, practices and methods of managing medical records is fundamental to acquiring patient support of telemedicine and the CPR.

The Equifax-Harris data supports Richard Caputo's recommendations for acquiring patient informed consent for inclusion of their records in an electronic information system. Richard Caputo suggests a framework for developing such policies specifically designed with computerized social service client (including patient) records in mind[19]. Caputo outlines five recommendations that should ground a hospital's approach to computerized medical records:

1. Patients should be informed of the existence of a computerized patient record system;

2. Patients should be informed about the use of information, its dissemination, to whom and in what form;

3. Informed patient consent should be required before inclusion in the system, except as otherwise legally required;

4. Patients should be permitted to inspect information about themselves, to correct errors and to add new information;

5. Patients should be permitted to expunge all or parts of their records, except as otherwise legally required.

The Office of Technology Assessment and the Privacy Working Group of the Information Policy Committee, Information Task Force make similar recommendations.[21,22]

These recommendations and the results of the Equifax-Harris survey directly influenced the formulation of and the research design to test hypothesis three. Patients will be informed of the existence of the electronic medical record and receive detailed

explanation of the testbed's policies, procedures and technical methods for maintaining the security of patient information in the electronic and paper-based records. Informed consent forms will include language and signature space for granting and withholding permission to include a patient's records in the computer system. Patients will also have the opportunity to complete written authorizations that subject to certain clearly defined circumstances limit the range of persons who have access to their records, the types of information that may be released, re-disclosure(that is, a third party giving patient information to a previously uninvolved party such as a central data bank), and new uses of data not explained as part of the original registration [20]. Patients will be informed that they have the right to inspect their medical record, correct errors and possibly add new information subject to legal restrictions with the aid of a person trained in these issues. Because patients should be able to get as much information as they require, all staff working with patients in the RDPM network will be trained in the project's security policies and procedures, practiced in explaining them and sensitive to the importance of patient confidentiality.

As John Fletcher notes, "Ethics is everybody's business, especially in regard to confidentiality".[23] Installing a computerized patient record is an organizational as well as a technological event. Its secure and ethical management must be woven into an institution's routine administrative life. Departmental and hospital policies on confidentiality should be reviewed to determine if revisions are necessary to manage computer-based records. Well developed discussions of the ethical principles and administrative policies on confidentiality and informed consent and of the security risks posed by computer-based patient records systems should be included in initial and continuing staff system training. Administration should develop ways to monitor staff compliance with security and confidentiality policies and should assess diligence in following them as part of staff annual performance evaluations.

3.0 Approach

Two experimental designs exist in this project, one for each hypothesis. Data about each hypothesis will be gathered for both electronic and paper-based versions of the Renal Dialysis Patient Management network as a part of the telemedicine testbed.

3.1 Approach to Test Hypothesis One:

Electronic telemedicine systems, when managed according to established information security practices, provide increased access to and maintain the security of patient information, compared to paper-based medical records.

Aim 1: Perform security risk analyses and implement risk management plans for the electronic and paper-based versions of the Renal Dialysis Patient Management network using access, authentication and encryption tools.

Step A. Conduct risk analyses

The investigators will perform risk analyses of the electronic and paper-based versions of the RDPM network to evaluate routine and extraordinary vulnerabilities to the threat of unauthorized disclosure of patient information, the threat of losses in the integrity of patient information and the threat of denial of service to authorized users. The risk analyses will identify and estimate the likelihood and importance of occurrence of threats based on the vulnerabilities of each version. They will include such issues as the effectiveness of physical and electronic access controls to the system, protection from data

disclosure, alteration and destruction, sufficiency and reliability of support systems and maintenance, adequacy of administrative support for security concerns, comprehensiveness of staff training and compliance with security policies and procedures. The risk analyses will include detailed estimates of expected loss in case of breaches in security of the RDPM systems as a result of identified threats and vulnerabilities.

To be most effective, security should be a consideration in the original design and implementation of a telemedicine project. As the investigators are an integral part of the development team for the Renal Dialysis Patient Management network, they will be able to integrate security measures and policies into the system from the beginning. The first step in analyzing and improving the security of each RDPM system will be to perform a detailed risk analysis. This will expose possible threats based on the vulnerabilities inherent in the Renal Dialysis Patient Management network and in paper-based and computerized medical record systems in general. Controls of these threats can then be developed, implemented, and evaluated.

The following sections outline the types of issues that must be examined.

Physical site and system security

- facility: Are there systems in place to protect the facility, such as regularly tested smoke detectors, fire alarms and appropriate extinguishers? For electronic systems, is the air-conditioning system adequate? Is the power supply reliable and sufficient and is an Uninterruptible Power Supply available in case of power outages? Where applicable, does an earthquake or storm warning system exist?
- physical access: Who has access to the facility, patient records, and equipment? How is access controlled and monitored? What types of measures are in place to protect access to the system and how easily can they be circumvented?

Data management

- access to data: Who has access to the patient records and who can modify or remove information? How is access controlled and monitored?
- storage: What kind of information is stored and for how long? Where are the patient records stored? What measures are in place to protect the data from unauthorized access, modification, destruction and disclosure? For electronic systems, is the data stored encrypted and are file integrity checks performed regularly?
- archiving: Does any archive storage of the data exist in a different medium and/or a physically separate location? Are such backups stored securely? How often is data archived? How easy and convenient is it to perform backups and retrieve information from backups when necessary?
- legitimate data destruction: How long is patient information kept before it is destroyed? What criteria are used to determine if a patient record is no longer needed, for example, the age of the record, or the patient's status in the system? How is obsolete data disposed of? Who manages and performs legitimate destruction of data?
- data transmission: What kind of information is transmitted as part of the telemedicine service, either in electronic or paper-based form? What communication channels are used and how are they secured? Is electronic data encrypted during transmission? Who is authorized to transmit data and how is access controlled?

Equipment, supplies and documentation

- location: see section a.
- availability: Is there a sufficient inventory of supplies to ensure availability at all times? Is equipment in good working order when it is needed? Does detailed documentation exist on all aspects of the system?
- quality control: How old are materials and are they in good condition? How is the quality and proper working order of equipment and supplies assured? What kind of maintenance/replacement program is in place? Is the documentation up-to-date and readable?

Personnel

- hiring and firing: How are employees selected? Do they have the necessary experience and expertise? Who makes personnel decisions and how are they made?
- training: What kind of initial and continuing training do staff members receive? Does it include training on security awareness, any security policies and their enforcement?
- preventing an "insider job": How is staff morale? Is there a potential for disgruntled employees who may endanger system security?

Procedures

- Are there established and documented procedures for performing clinical and maintenance tasks? How do these procedures affect the overall security of the system? Are day-to-day procedures performed in accordance with security guidelines? (e.g. Are passwords used appropriately?)

Administrative

- management support: Is management knowledgeable and supportive of security issues? Are adequate resources allocated to maintain an acceptable level of security?
- responsibilities: Who has the responsibility for maintaining system security? Who decides who has access to what records and system components?
- policies: Is there an adequate security policy? How and how well is it enforced? Is there an appropriate inter-institutional policy? Does a current disaster recovery plan exist?
- insurance: Is the telemedicine system and the institution insured against potential breaches of security, disasters, etc. ?

Software

- operating system: What types of access controls does the operating system provide? Are passwords required and monitored? Is the operating system adequately maintained and updated when necessary? Are audit logs in place and are they regularly monitored?
- applications: How are application programs installed and maintained? Who is responsible for software maintenance? Are measures in place to detect unauthorized access or changes to computer files?
- virus protection: Is virus checking used and updated regularly?

Computer hardware

- maintenance: Is there an adequate maintenance program in place? Is maintenance personnel knowledgeable and available when needed? How often and how thoroughly is the computer hardware maintained? Is hardware regularly tested?
- how old, adequate for current needs, expandable for future needs

Telecommunications

- remote access: What telecommunications (e.g. modem over telephone lines, Internet) can be used to access the system? Who is allowed remote access? How is remote access controlled and monitored?
- protection against denial of service: How are the telecommunications lines protected? Are telecommunications dependent on third parties or controlled entirely by the project management? What kind of redundant communications methods are available?

After the risks and vulnerabilities of each system have been thoroughly analyzed, countermeasures must be found to combat the identified threats. These will be developed based on standard information security practices. Such controls may include technical solutions, procedural changes, and the development of a comprehensive security policy. Each potential countermeasure will be examined closely for feasibility, ease of implementation, effectiveness, and cost. Based on this evaluation, the investigators will then propose a set of countermeasures to be implemented. The results of these detailed risk analyses will form the basis for the risk management strategies for each of the RDPM systems and for the testbed as a whole.

Step B. Develop plans for managing identified risks

Once the risk analysis is completed for the paper-based and electronic versions of the Renal Dialysis Patient Management network, the investigators will develop a strategy to manage the identified risks. This plan must address the threats and vulnerabilities found during the course of the risk analysis and focus on those controls determined to be most effective. It will be made up of several parts including an implementation plan, a comprehensive security policy, and a test plan to ensure that the implemented measure work.

Implementation plan

From the results of the risk analyses, certain measures will be chosen as the most appropriate for managing the identified risks. The implementation plan will enumerate the staff, equipment and general operating requirements necessary to apply these measures. While the specific nature of the measures depends largely on the results of the risk analyses, some general requirements exist for any implementation plan. It must be feasible and not unduly disrupt system operation. If an implemented measure does affect the system to an unacceptable extent, it must be possible to remove that control. Security measures should not be forced on users; rather, users should be made to understand the necessity and rationale behind each measure. In any security implementation there should exist some redundancy in knowledgeable staff, so that the system does not depend solely on any one person.

Security policy

The investigators will develop a comprehensive security policy, which will include a general stance on patient rights to confidentiality and privacy, and on the responsibilities of the health care providers and other staff participating in the telemedicine project. It will outline procedures to be performed in order to ensure the security of the system, specific details of which will be determined by the results of the risk analysis. The security policy will clearly assign responsibility for different aspects of system security. An enforcement

strategy will ensure that all participants know the rationale behind the policy and what to expect if they fail to comply.

Because telemedicine applications on the NII can cause patient data to be shared among distinct health care institutions, they pose the problem of protecting patient information across institutional boundaries. Therefore, a clear agreement must exist between cooperating institutions about who bears responsibility for what data and how patient information belonging to another institution must be protected. The investigators will develop and implement such an inter-institutional agreement with researchers at Penn State University as part of the security policy for the testbed.

In developing the security policy, the investigators will examine any existing institutional policies in order to remain in compliance with broader institutional guidelines. They will also utilize templates of security policies available on the Internet and in the information security literature so that they can take advantage of the existing knowledge base. Using these tools, the investigators will define guidelines to be followed by all staff when operating within the Renal Dialysis Patient Management network.

Test plan

To ensure that the chosen countermeasures are effective and worthwhile, the revised system must be thoroughly tested. Several avenues for testing are available to the investigators.

The most important method of testing will be careful observation of the systems in operation. The investigators will look at how well the new security measures are integrated into the operation of the system and how effective they are in preventing security breaches. If a security breach should occur, it will be carefully analyzed to see which, if any, security measures were inadequate, how it could have been prevented, and if its severity or likelihood of repetition warrants further security measures.

For electronic systems, many software tools for testing system security are freely available on the Internet. Such tools can check for the existence and the quality of passwords on a computer system. They can also look for vulnerabilities in installed programs that can be exploited to gain unauthorized access to the system.

Step C: Manage identified risks

The investigators will proceed according to the implementation plan developed in Step B to manage the previously identified risks of the electronic and paper-based versions of the Renal Dialysis Patient Management network.

Step D: Compare the actual system with results expected from Step A

Once all the security measures have been implemented, the electronic and paper-based versions of the RDPM network must be re-examined. Did the implemented changes produce the expected and desired results? Has an acceptable balance between security and utility been achieved? Are users and management satisfied that the system functions properly and that the confidentiality and integrity of patient records is assured? The investigators will answer these questions by performing another set of risk analyses on the

RDPM systems. Based on those results, they will determine how and whether to proceed further.

Aim 2: Develop and compare usability-security curves of the electronic and paper-based Renal Dialysis Patient Management systems.

Step A: Develop usability-security curves

Using data from the risk analyses performed in Step A of Aim 1, the investigators will develop a usability-security curves summarizing identified threats and how vulnerabilities in the electronic and paper-based versions of the RDPM network can be exploited.

Step B: Compare the usability-security curves

The investigators will compare the electronic and paper-based versions of the Renal Dialysis Patient Management network using principles such as ease, effectiveness and cost of risk management.

Aim 3: Review, implement and evaluate the impact of access, authentication and encryption tools for enhancing security of DICOM based communications on the Internet.

Step A: Review existing security tools

The investigators will perform a thorough review of existing access, authentication and encryption tools for the Internet, which may be applied to DICOM based communications.

Step B: Select, install and evaluate tools in testbed

Based on the results from Step A, the investigators will select appropriate security tools and apply them to DICOM based communications throughout the testbed and over the Internet. The performance of these tools in providing access controls and secure transmission of data will be evaluated.

Step C: Report results

The investigators will report their experience in applying existing security tools to the DICOM standard to the Working Group VI Ad Hoc Committee on Security of ACR-NEMA with recommendations about potential additions to the DICOM standard.

3.2 Approach to Test Hypothesis Two

When properly informed about the institution's policies, procedures and methods for maintaining the confidentiality of their medical records, patients will agree to using telemedicine systems and to storing their information in an electronic medical record.

Aim 1: Develop patient educational materials in video, written and oral formats explaining the testbed's policies, procedures and methods for maintaining the confidentiality of medical records in the electronic and paper-based systems.

Step A: Prepare patient education material about security management in oral, written and videocassette formats on basis of risk assessment and security management plan;

Step B: Conduct a pretest of effectiveness of patient educational material;

Step C: Revise patient educational material in light of results of pretest;

Aim 2: Include the educational material developed in Aim 1 as part of the process for obtaining consent of a test sample of patients to participate in the electronic RDPM network and request consent to use the telemedicine and computerized patient record systems to manage their information.

Step A: Develop schedule for interviewing patients about reasons for choosing either electronic or paper-based information management system;

Step B: Incorporate patient educational materials about security management into process of informed consent and submit to Institutional Review Board for final approval.

Step C: Train relevant project staff in correct methods for obtaining patients' informed consent or refusal to participate in the telemedicine testbed projects and for administering interview schedule about choice of information management method.

Step D: Administer instrument to all patients as part of obtaining informed consent for participation in telemedicine demonstrations.

Aim 3: Obtain explanations for patients' consent or refusal to use the telemedicine and computerized patient record systems to manage their information.

Step A: Interview patients about reasons for choosing either electronic or paper-based information management system;

Step B: Evaluate hypothesis in light of data on patients' decisions and reasons for choosing either electronic or paper-based information management system.

4.0 Methods

4.1 Methods to Test Hypothesis One

Electronic telemedicine systems, when managed according to established information security practices, provide increased access to and maintain the security of patient information, compared to paper-based medical records.

4.1.1 Perform risk analyses

For each risk analysis, the investigators will apply the same methods to the system under consideration. In each case, the steps of the risk analysis will be as follows:

- determine the assets of the system
- evaluate the threats and vulnerabilities
- calculate expected loss
- determine possible countermeasures against the discovered threats and vulnerabilities
- perform a cost/benefit analysis of the countermeasures
- make recommendations on most effective countermeasures

To gain information on the assets, risks and vulnerabilities, the investigators will develop a security survey tailored to each system and use it to interview its users. For each evaluation, the security survey will address those areas discussed in Section 3.1 as they apply to the particular system. Users will be asked to evaluate system security on the basis of their own expertise and point of view. The investigators will also employ objective observation of each system, factual data and anecdotal information related to any previous security breaches.

Perform risk analysis on paper-based RDPM network

For this risk analysis, the security survey will focus on the physical security of the dialysis units at Union Station Plaza and Thomas Jefferson Street, the Department of Nephrology at GUMC, and the testbed including the Department of Radiology. Users will also be asked to describe and evaluate the procedures in place to safeguard the confidentiality and accuracy of their patient records. The survey will be administered to administrative staff and managers of the dialysis units and radiologic patient records, nurses, and physicians caring for dialysis patients. The investigators will observe the operation of the testbed to identify all assets, threats, and vulnerabilities. The ascertained risks and countermeasures will be evaluated and reported as described in Section 2.1.

Perform risk analysis on electronic RDPM network

The risk analysis of the electronic RDPM network will analyze the physical security of all the facilities, as well as the computer and communications equipment throughout the testbed. This includes the MD/TV workstation at each remote dialysis unit and its interface to the dialysis machines, the Nephrology Department's telemedicine workstation, the communications lines between the units, the Radiology Department's network and its patient record management systems, and the home teleradiology and home telenephrology services. This risk analysis and its concomitant security survey will also examine the way patient data is stored and accessed electronically. Administrators, nurses and physicians will be surveyed as in the analysis of the paper-based system, along with technical staff involved in installing and operating the telemedicine systems in the testbed. The investigators will perform detailed observation of the on electronic RDPM network to

verify and elaborate on the results of the security survey. Once again, the identified risks and countermeasures will be evaluated and reported as described in 2.1.

4.1.2 Develop risk management plans

As described in Section 3.1, the investigators will analyze the results of the risk analyses and develop plans for managing the identified risk using the countermeasures shown to be most effective in the risk analyses.

4.1.3 Implement the risk management plans

The implementation will proceed according to the implementation plans developed in the previous section, which depend largely on the results of the performed risk analyses.

4.1.4 Compare the results found in the actual system with those expected

Once all the security measures have been implemented, the electronic and paper-based RDPM systems will be re-evaluated the investigators to see if the expected goals have been achieved and if the systems adequately assure the confidentiality and accuracy of patient records.

4.2 Method to test Hypothesis Two

When properly informed about the institution's policies, procedures and methods for maintaining the confidentiality of their medical records, patients will agree to using telemedicine systems and to storing their information in an electronic medical record.

The population of patients who agree to participate in the RDPM network will be randomly divided into two groups. Patients in both groups will be informed that their medical information will be transmitted via a telemedicine system and stored in an electronic medical record given their consent. Patients in the test group will also receive a detailed explanation of the security policies, procedures and technical methods being used to protect their records. Patients in the control group will receive no such explanation. All patients will be asked to consent to having their records included in the electronic record. Patients who refuse will have their information stored in the paper record.

	received security explanation	did not receive security explanation
consented to electronic record		
did not consent to electronic record		

DIAGRAM D

Patient responses will fall into cells of a 2x2 cell matrix as shown in Diagram D. If there is no effect of giving or not giving an explanation of security measures, patients should be observed in each cell in approximate accord with the row and column marginal frequencies. To the extent that the distribution of patients deviates from this, particularly with patients concentrated in the cells corresponding to received security explanation and consented to electronic record, and did not receive security explanation and did not consent to electronic record, it could be concluded that the presence or absence of a security explanation is associated with mode of participation in the RDPM network. The chi-square test for differences in probabilities of a 2x2 contingency table will be used to evaluate the

data. The quantitative analysis of patient choices will be complemented with qualitative analysis of data from scheduled and open-ended interviews with patients about their reasons for consenting or refusing to consent to having their health information stored in the electronic record.

5.0 Conclusion

The following deliverables will produced at the times indicated.

6 months

- Risk analysis of paper-based RDPM system (Hypothesis One, Aim 1, Step A)
- Risk analysis of electronic RDPM network and the testbed (Hypothesis One, Aim 1, Step A)
- Report on evaluation of existing security tools as applicable for DICOM communications (Hypothesis One, Aim 3, Step A)
- Risk management plan for the electronic and paper-based RDPM networks and the testbed (Hypothesis One, Aim 1, Step B)
- Patient educational materials, including videotape, brochure and materials for oral presentation (Hypothesis Two, Aim 1)

12 months

- Report on usability-security curves of the electronic and paper record (Hypothesis One, Aim 2, Step A)

18 months

- Report on the implementation of the security measures for the paper-based RDPM system (Hypothesis One, Aim 1, Steps C, D)
- Report on the implementation of the security measures for the electronic RDPM network (Hypothesis One, Aim 1, Steps C, D)
- Results of comparison of the paper-based and electronic versions (Hypothesis One, Aim 2, Step B)
- Preliminary results of patient interviews on their willingness to participate in the electronic RDPM network (Hypothesis Two, Aim 2, Steps A-D, Aim 3, Steps A, B)

24 months

- Report (also to WG VI Ad Hoc Committee on Security of ACR-NEMA) on application of security tools to DICOM communications (Hypothesis One, Aim 3, Steps B, C)

32 months

- Final report on success of risk management strategies in paper-based and electronic RDPM systems and the testbed. Results of comparison between paper-based and electronic systems. (Hypothesis One)
- Final report on patient interviews, including statistical analysis of results and qualitative analysis of patient responses (Hypothesis Two)

- Evaluation of contract and recommendations for further study.

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Akamai Annual Report

Chapter 6

Clinical Economic Modeling in Telemedicine

6.1 Clinical Economic Modeling of a Renal Dialysis Patient Management Network

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Abstract

The Imaging Science and Information Systems (ISIS) Center of the Department of Radiology at Georgetown University Medical Center (GUMC) in conjunction with the Clinical Economic Research Unit (CERU) is developing a clinical economics model for the evaluation of a Renal Dialysis Patient Management (RDPM) Network. In this paper, we develop the clinical economic model and explain how it will be applied to the assessment of the RDPM network and its impact on hemodialysis patient management and care.

1.0 Introduction

The Renal Dialysis Patient Management (RDPM) network is a project undertaken by the Imaging Science and Information Systems (ISIS) Center of the Department of Radiology at Georgetown University Medical Center (GUMC) in conjunction with the Clinical Economic Research Unit (CERU) of the Department of Medicine. The network links Georgetown University Medical Center, one of the two remote outpatient kidney dialysis clinic, and a nephrologist's home.

The RDPM network will test the general hypothesis that by facilitating electronic interactive communication among tertiary level physicians and patients at other institutional levels, telemedicine will improve the quality of patient care and lower costs to patients, physicians and the health care system. This paper describes the clinical economic model based on RDPM network service.

The objective of this study is to demonstrate that by improving access of physicians to patient data and of the patient to their physician, telemedicine will improve the quality and lower the cost of health care. This project will test this general hypothesis in a Renal Dialysis Patient Management (RDPM) service that links one primary outpatient care facility, a nephrologist's home, and a tertiary center through telemedicine. This clinical protocol will improve the quality of care through an "electronic comprehensive consultation" (ECC), an interactive platform that allows for real-time quality assessment and monitoring.

We therefore offer the following hypotheses specifically applied to dialysis service:

1) By providing the nephrologist with real-time information about patients' health status, RDPM will improve outcomes as measured by the ratio Kt/V_{urea} in managing the routine and emergency medical care of kidney dialysis patients.

2) By giving patients and nephrologists the opportunity to interact over a video-conferencing network during dialysis sessions, the RDPM will increase the time patients spend on dialysis.

3) By improving the Kt/V_{urea}, the RDPM will:

a. reduce the frequency of medical events,
b. improve the patient's quality of life
c. reduce costs to patients and the health care system.

4) By reducing variance in the Kt/V_{urea}, the use of the RDPM will enhance compliance of kidney dialysis centers with the quality assurance requirements of regulatory agencies such as HCFA (Health Care Financing Administration).

The general aim of this aspect of Project Phoenix is to develop a clinical economic model quantifying the impact of the RDPM network on patient quality of care and costs in kidney dialysis service. We will accomplish the following specific aims towards that effort:

1. Determine the impact of telemedicine on the processes of care in renal dialysis service including compliance of dialysis centers with established standards of care, duration and frequency of patients' dialysis sessions.

2. Determine the impact of telemedicine on outcomes of care in renal dialysis service including Kt/V_{urea}, survival, hospitalization and other indicators of morbidity.

3. Test renal dialysis patient satisfaction.

4. Develop and test cost of care and impact model on Medicare and the health care system.

2.0 Clinical Rationale

Patients with uremia or End-Stage Renal Disease (ESRD) retain in their bodies breakdown products of protein metabolism, such as urea and creatinine as well as other solutes such as sodium and potassium. They lose the ability to excrete water and lose essential hormones produced in the kidney. In order to eliminate these breakdown products and solutes, patients undergo hemodialysis, a mechanical process whereby blood is removed from a patient, cleansed of unwanted impurities and returned to them. Hemodialysis is the major form of renal replacement therapy for patients with ESRD and carries in the US a 22% first year gross unadjusted mortality, a figure which greatly exceeds that of Europe (14%) or Japan (12-14%)[1]. Several studies have suggested that the higher annual mortality rate for hemodialysis patients in the United States compared with those in Europe and Japan is due to <u>decreased dialysis time</u> and <u>inadequate dialysis dose</u>[2].

<u>The Kt/V_{urea} Ratio and Serum Albumin in End-Stage Renal Disease</u>

One of the main surrogate markers of the quality of clinical services for individual patients undergoing dialysis is the Kt/V_{urea} ratio-a global standard for the measurement of the quantity of dialysis delivered. Kt/V_{urea}, a dimensionless number relating dialysis urea clearance (K), time on

dialysis (t), and the volume of the urea pool (V - or whole body water), is significantly related to patient survival[3] and morbidity[4]. The higher the value of a patient's Kt/V_{urea} ratio, the better the outcome and the lower the cost of treatment regardless of the primary reason for ESRD necessitating dialysis. Studies[5] have shown an increased relative risk of death for Kt/V_{urea} values of less than 1.2. HCFA, through the regional dialysis networks, recommends a Urea Reduction Ratio (URR) of at least 65% or a Kt/V_{urea} minimum of 1.2. GUMC seeks a Kt/V_{urea} of 1.5. Serum albumin level is also correlated with both morbidity and mortality[6,8]. A serum albumin below the reference value of 4 g/dl, is associated with a step-wise relative risk of death. When serum albumin falls below 2.5 g/dl the relative risk of death is increased 18.5 fold[7]. It has been shown also that there is a positive correlation between Kt/V_{urea} and serum albumin concentrations[3]. As will be described below, Kt/V_{urea} ratio and serum albumin levels directly affect the cost of medical care of kidney dialysis patients, including hospitalization.

ESRD and Medicare Costs

ESRD is covered by Medicare to a total cost of $8 billion per year. There are over 150,000 patients on dialysis or receiving transplants from the Medicare ESRD program.[9] Hemodialysis costs on average $30,000 per year per patient. Cost varies depending on the intensity, length and frequency of the adverse medical events leading to hospitalization. As shown in the USRDS study[1], hospital days rates per patient year at risk are 15.8 days per year.

Limitations of Current Clinical Service

An increasing number of dialysis facilities are outpatient facilities situated at a distance from any physician and regularly staffed with nurses and technicians. Nutritionists and social workers visit only once per week. The clinics are usually open from 7:00AM - 9:00PM; 24 hour service is not available because it is too costly to staff. Physicians make rounds on patients at variable intervals from weekly to monthly depending on the practice of the institution.

Management of Routine Dialysis: At the beginning of a routine dialysis session, the technical/nursing staff examines each patient to determine vital signs (blood pressure, heart rate, respiratory rate, temperature) and to seek evidence of pulmonary edema (detected by auscultation of the lung bases), cardiac abnormalities (heart rate and apical auscultation), and vascular access (graft or fistula) dysfunction - the latter by inspection and auscultation. Any abnormalities are noted in the chart and brought to the attending physician's attention during rounds. At about nine intervals during the dialysis session, the nurse records the dialysis parameters in the patient chart, including automated patient blood pressure; venous pressure; arterial pressure; transmembrane pressure; blood flow rates; dialysate flow rates, conductivity, and temperature; ultrafiltration rates and sodium delivery. Patients undergoing hemodialysis are usually dialyzed three times a week with each session lasting about four hours. They are attached to a dialysis machine using a shunt giving vascular access usually through the forearm. While on dialysis, patients watch television, read books or sleep. At times patients frequently feel acute boredom and extreme restlessness. These conditions reduce the amount of time that patients spend on dialysis. Patients skip appointments and end dialysis sessions early. When the time patients spend on dialysis decreased, Kt/V_{urea} decreases. Recent (as yet unpublished) data has shown a 14% increased mortality if a patient misses one of the three dialyses prescribed per week (occurring in 7% of patients nationwide), while about 20% patients consistently shorten the dialysis time by 10 minutes or

greater. (Port F, personal communication, 1996). Another study clearly indicates that short-time dialysis is correlated with mortality.[10]

When the attending physicians make rounds, they spend 10 to 20 minutes with each patient depending on their familiarity of that patient's condition. Physicians perform a limited patient physical examination and review biochemistry and hematology tests. Physicians carefully evaluate the status of patients with disorders of bone metabolism, cardiac disease and hypertension and dialysis prescription. During this time, physicians also counsel patients on the complexities of their problem and the importance of compliance with their prescribed dialysis.

Management of Emergencies: Renal dialysis patients commonly experience a variety of acute, chronic and emergency conditions requiring physician attention. Acute conditions include pulmonary edema, pneumonia, pericardial effusion and pleural effusion. Chronic complications include metabolic bone disease, arthritis, and amyloidosis. Patients sometimes experience acute symptoms such as shortness of breath, fever or hypotension awaiting or following dialysis . Emergency situations arise daily in dialysis units - ranging from minor to life-threatening. Common emergencies include bleeding or clotted fistula, cardiovascular collapse (heart attack, arrhythmia, volume depletion, bleeding, shock), infections, drug reactions, and hypo- or hyperglycemia. Emergencies are mainly patient originated (intercurrent illnesses), but dialysis related emergencies do arise such as pyrogenic reactions to bacterial products, changes in conductivity, fluoride intoxication, over-heparinisation, ultrafiltration malfunction and air embolism.

A variety of tests and measurements are routinely performed to provide attending physicians with information necessary to manage these conditions. Radiography and ultrasound are used to detect both acute and chronic complications of chronic dialysis treatment. Chest radiographs can demonstrate pulmonary edema, pleural effusions and pneumonia. Ultrasound can be used to detect pericardial effusions in patients who are hypotensive. Shunt evaluation studies (angiographic or ultrasound) are also occasionally needed. Stenotic or thrombosed shunts may also benefit from transvascular image guided treatment. Attending physicians may avoid some types of emergency with adequate longitudinal information consulted during patient rounds. This data is currently stored in various places throughout the medical center, not at the dialysis clinic. If emergencies or acute problems occur when the attending physician is off-site, it is impossible to provide real-time access to the patient or patient information needed to manage the situation. When the patients threaten to shorten their dialysis session, the physician cannot provide reassurance or encourage them to complete dialysis.

The paper-based renal dialysis service suffers from the following limitations:

- Patient access to the physician is limited.
- Physician access to patient data and the patient is limited.
- Data necessary to manage the patients are widely dispersed.
- Remote real-time acquisition and transmission of relevant data is not possible.
- Physician is unable to reassure patients threatening to shorten their prescribed dialysis time

3.0 The Clinical Economics Approach

The evaluation of new medical technologies--such as telemedicine--has traditionally focused on accuracy, reliability and safety. In telemedicine, studies have explored technologic parameters and technical ability to implement specific types of data transfer. Yet these evaluations were limited in

assessing the effect of technologies on the health care system. Furthermore, in an era of increasingly constrained resources, these assessments neglected the costs of medical services and technologies. Health care researchers in a variety of disciplines have recently developed new techniques for evaluating the economic impact of clinical care and medical technology. Clinicians, economists, epidemiologists, operations researchers and others have contributed to the field of "clinical economics," an evolving discipline focused on studying different approaches to patient care and treatment and the influences of these approaches on the resources consumed in medical care.[11]

Clinical economics provides a useful background for addressing a number of health policy questions, and the assessment of new telemedicine programs is an ideal example of the application of clinical economics to health policy making. Policy decisions can be made at three principal levels, and clinical economics can inform each of them. First, at the level of public policy decisions, decision makers must use the results of clinical economics studies on costs and outcomes to determine broad societal decisions, such as how much money to invest in new initiatives, whether to include them as part of a basic benefits package for public-sponsored insurance plans, when to provide coverage for these services in programs such as Medicare and Medicaid, when to approve new technologies for their safety and efficacy, and how to prioritize these new technologies for development and evaluation. A second level of health policy decision making is at the level of health care systems, such as hospitals, managed care organizations, and large physician groups. These organizations must make decisions about which services to purchase, which drugs to include in their formularies, where to deploy new technologies, and what kind of staff to recruit in order to apply the new technologies. Studies of the cost and effectiveness of services such as new technologies are critical in aiding health care organizations to decide whether and when to purchase and implement new technologies such as telemedicine. The third level of health policy decision making is at the level of the individual clinician and patient. Clinical decisions should be guided by information on cost and outcome, and clinicians' decisions to use particular technologies, as well as patients' decisions about whether to undergo or participate in the use of new technologies, can be guided by information on costs and outcome.

Clinical economics can be used to evaluate technologies by taking advantage of its interdisciplinary character. On one hand, clinical economics builds on the conventional methodology of accounting and economics, using standard as well as new methods to identify the cost of providing services from various perspectives and for various kinds of costs. In addition, clinical economics applies disciplines related to clinical research, such as clinical epidemiology, outcomes assessment, and decision analysis in order to determine the effectiveness of clinical services. Balancing costs and outcomes is the essence of clinical economics, and rigorous assessment of these costs and outcomes is the underlying methodology of clinical economics research.

As new technology emerges, a quandary arises for developers of the new technology, which was pointed out in the 1995 Physician Payment Review Commission Report. New technologies must be evaluated at several steps along the process of their development. At early stages, technology assessment, including clinical economics, must be applied in order to determine whether further development costs are likely to be fruitful. At a second stage, safety and efficacy of new technologies, particularly their usefulness to clinicians and to patients, need to be assessed. Once the technology has been demonstrated to be efficacious, decision makers need to carry out further evaluations to determine whether the service should be reimbursed (from the perspective of third-party payers) or implemented (from the perspective of health care providers). At the same stage, patients need to decide whether they are willing to be participants in the application of a new technology. At a later stage, once the technology is mature, its appropriate dissemination and reimbursement levels need to be determined. In our staged approach[12] to the assessment of

telemedicine we specifically examine different developmental stages to recognize the role of technology assessment in fostering the development of this new and emerging technology and at the same time providing a formal framework under which investigators can continue to pursue and develop their applications. At the same time, this staged approach allows us to recognize that telemedicine concepts are still experimental and not yet being considered for widespread adoption or use. Once the field matures, we can use these techniques of economic assessment to help inform decision-makers about specific telemedicine applications so they can decide whether the applications should be reimbursed or adopted.

Clinical economics is concerned with more than the costs of telemedicine treatment. Cost effectiveness analysis calculates costs for specific levels of clinical benefit and explicitly compares the cost of medical technologies to the benefits received by patients. Economic evaluation of clinical trials includes assessment of the quality of life perceived by patients receiving specific medical services and allows for the assessment of the quality of clinical services received by the patients. Assessment of quality for new medical services and new medical technologies must be considered in light of the most appropriate clinical considerations for the new technology. For example, telemedicine can improve quality of care by providing access to more specialized consultation services with the world's experts in specific clinical disciplines. At the same time, telemedicine could compromise quality of physician and patient interactions if they become mechanized or if the technology itself has adverse impact on patients.

Our clinical economic model depends on the following three parameters:

- Access
- Quality
- Cost

3.1 Access

In this application, access refers to:

Patient access to doctor: This type of access includes interactive video conferencing between the physician and the patient. A distinction will be made between total videoconferencing time and face to face time. This will be determined by the amount of time the patients are supervised by a nephrologist, including the amount of direct review from the nephrologist for each patient and compared with the control group. We will gather special data about patients threatening to shorten their dialysis sessions. We plan an intervention in which the physician consults with patients threatening to shorten their dialysis sessions using the videoconferencing capability of the telemedicine workstation.

Doctor access to patient information: This type of interaction will be measured by the frequency in which the doctor accesses the database containing the patient folder as well as the time spent. This will be compared to the control group times where the doctor reviews patient charts, x-rays, lab values, etc.

3.2 Quality of Care

In this section we describe our methodology for assessing the impact of increased access through telemedicine on the quality of care. We will measure quality of care through the impact of telemedicine on processes of care and outcomes of care in dialysis.

Measures of Processes of Care:

- -Frequency of medical events
- -Duration of hemodialysis treatment time
- -Frequency of hemodialysis sessions

-Compliance with established standards of care
-Patient compliance with prescribed dialysis

Measures of Outcomes of Care:
-Clinical Outcomes
Kt/V_{urea}
Serum Albumin
Morbidity
Mortality

-Preference Based Outcomes
Quality of life (health status, patient preference)
Patient satisfaction

Processes of Care

We will measure the process of care, including compliance with standards established by regulatory agencies (such as HCFA) but also patient compliance with their prescribed dialysis. HCFA has set standards of care for dialysis services with Kt/V_{urea} minimum of 1.2 . The first process relating to compliance with established standards of care refers to the variability that exists between sites in the quality of care dialysis service delivered as measured by the Kt/V_{urea}. The second compliance measures the degree of patient compliance with their prescribed dialysis. This is measured by the frequency and duration of their sessions as well as other parameters to be determined by a group of nephrologists selected in Phase I of the study.

Outcomes of Care

We plan to measure outcomes of care, both clinical and preference-based measures. This would include Kt/V_{urea}, serum albumin, mortality, adverse events or other indicators of morbidity, patient satisfaction, health status measures (e.g., Quality of Well-Being (QWB),[13] EuroQuol,[14] Sickness Impact Profile (SIP),[15] etc.) to be described later. Outcomes will be measured at several levels. In Phase 1, the investigators will test several quality of life measures, including QWB, EuroQuol, and SIP to determine a metric whereby health status outcomes can be determined. These will help to weigh the years of life of survival by a quality indicator in order to determine a metric such as quality adjusted life years.

3.3 Cost Derivation Model

3.3.1 Cost Perspectives

Costs may be calculated from different perspectives: from the viewpoint of the patient, caregiver, physician, payer, or society. Although telemedicine may be expected to improve quality, it may also reduce costs. There may also be transfers of costs, such as higher costs of outpatient dialysis but lower costs of hospitalizations for patients who have fewer complications.

Medicare Costs: One important measure of these costs, but not the only measure, is the cost incurred by Medicare. Because Medicare is the largest payer for dialysis, its perspective is important . However, the cost of the care of patients with end-stage renal disease is also important from the perspective of the caregiver and the patient himself or herself. Thus, a cost derivation model will be developed that will include not only Medicare costs and other ways of analyzing the

economic impact of hemodialysis and the effect on hemodialysis of telemedicine. Measures to be used will include the number of emergency visits to the hospital, tests ordered, and hospitalizations.

Patient Costs: The cost of care for patients undergoing dialysis will be measured in this study. Because much of dialysis is capitated by the Medicare program, long-range savings will occur only after operating costs drop, making it possible for Medicare to reduce its payment without causing providers to lose money and risk decreasing access to dialysis care for patients with end-stage renal disease. In addition, there are some costs incurred for patients on dialysis that are paid outside the capitation amount, including hospitalizations and certain physician services. These costs could be enumerated to determine whether the telemedicine intervention causes a reduction in these costs. In addition, we will evaluate the impact of dialysis on the patient and caregiver from the perspective of time lost from work. These are not direct medical expenses, but may be substantial. In addition, we will evaluate mortality rates, although we do not anticipate calculating the indirect costs of mortality from ESRD.

3.3.2 Our Cost Model

The cost derivation model for patients in endstage renal disease will be used to enumerate total costs, emphasizing those costs most likely to be affected by telemedicine. Initial stages of the project will develop the cost model further, in consultation with nephrologists, individuals with expertise in organizing dialysis settings, and HCFA authorities. The cost model will include several parameters, built on the fundamental paradigm of enumerating the number of services provided to patients on hemodialysis and estimating the cost of each of those services. Because price is the cost only to those who pay at the level of charges, we will need to adjust charges and price for appropriate discounts and to otherwise estimate the true cost of delivering services from the perspective of society, the patient and caregiver, and the third-party payer. We will also attempt to measure the costs of the telemedicine intervention, although estimating the cost of a new technology may overestimate the ultimate cost of that technology once it has been fully developed and disseminated. Nonetheless, a sensitivity analysis can be performed to estimate the impact of further diffusion on the cost of telemedicine. In addition, the analysis can determine if there are savings in direct patient care from a telemedicine intervention, how much telemedicine could cost before those cost savings would be eliminated. At this point, the principal advantage of telemedicine would be whatever effect it has on the quality of care provided, whether that be process or outcome parameters.

3.4 Experimental Design

Two outpatient dialysis units (Thomas Jefferson Place, Union Station Plaza), one tertiary care site GUMC and one physician home will be used for this experiment. One outpatient clinic will be selected as a telemedicine site while the other will be designated as a control site. Patients will be assigned to either treatment arm (telemedicine vs. control) based on whether the site to which they are originally assigned for dialysis is a telemedicine site or not. Patients at the telemedicine site will then be given the choice to participate or not in the study. Based on conservative estimates, we expect to receive around 50 patients for each site by September 1996. The nephrologist will physically visit the control site and the telemedicine site once a week as required by District of Columbia laws. However, the visit to the telemedicine site will involve aspects of our Electronic Comprehensive Consultation (ECC) such as data acquisition, retrieval and storage in an electronic format while the visit to the control site will be all paper based. Patients and health care workers in the telemedicine site will have access to the nephrologist at all times (at home as well as at GUMC) during common and acute emergency situations while patients in the control group will follow usual operational procedures described in the Rationale Section. Appendix I describes the operational procedures and clinical protocols that have been established to be followed by the

health care worker on each patient visit. Data will be entered into the patient session folders in the database and then on a weekly basis into their master folder.

3.5 Phasing

The technical efficacy of a new technology has to be established before the impact on patient outcomes and cost can be measured. Phase I of our study will allow us to test and optimize the communications infrastructure, develop a serial interface to download dialysis parameters from dialysis machine to the telemedicine workstation and test accuracy and reliability of the measurements once technical system operational.

During Phase I, other preliminary aspects will also be decided such as assignment of patients to telemedicine/non telemedicine groups, optimization of the telemedicine workstation to suit patient and physician needs and to capture necessary data, and testing of several quality of life measures, including QWB, EuroQuol, and the SIP in terms of their appropriateness to the specific application to determine a metric whereby health status outcomes can be determined in Phase II.

Phase II: Phase II (consisting of 18 months data collection, followed by 6 months of data analysis) will be devoted to testing the impact of telemedicine on quality of care delivered, patient satisfaction and costs. While data analysis will be done in the final six months of the contract, data will continue to be added for further analysis after the completion of the project.

4.0 Methods

4.1 Data Collection

All data collected will be stored on the telemedicine workstation in the appropriate patient folder of the database.

4.1.1 Access Data Collection

Data about access information will be measured at each session and entered into the database under the patient's folder. Automatic data collection will include initial consultation start time, end time, etc. The automatic data collection will also include the ability to determine the amount of historical information accessed as well as the type of data retrieved (lab values, EKGs, x-rays, etc.). This automatic data collection strategy will be optimized in Phase I of our study.

We will pay special attention to situations when patients threaten to shorten their dialysis sessions. Under such circumstances, the nurse will contact the nephrologist and arrange an immediate consultation with the patient using the videoconferencing capability of the telemedicine workstation. Data will be collected on the length of time patients remain on dialysis after a videoconference with the nephrologist. We will analyze both the amount of extra time patients spend after a videoconference and the difference in the average spent on dialysis between the telemedicine and the control groups of patients.

4.1.2 Quality of Care Data Collection

Quality of care as previously described in terms of processes and outcomes of care will be determined by looking at the following instruments:

Processes of Care Evaluation Instruments

Compliance with Established Standards of Care: Average Kt/V_{urea} ratio and albumin values will be monitored for all patients in both telemedicine and control dialysis units, and in individual patients.

Duration, Frequency of Dialysis and Compliance with Dialysis Prescription: The effectiveness of the care received will be measured by duration of dialysis and frequency of dialysis received. This will allow us to determine the total amount of time patients have spent on dialysis thereby affecting Kt/V_{urea} ratio. This will also determine how well patients are complying with their prescribed dialysis program. As above, emergency situations when patients threaten to shorten their dialysis sessions will also be analyzed.

Frequency of Medical Events: The frequency of medical events such as hospital admissions, visits to the ER, outpatient visits will be monitored through patient charts. The impact of telemedicine on reducing the frequency of medical events will thus be monitored.

Outcomes of Care Evaluation Instruments

Clinical Based Outcomes: Mortality, morbidity and other adverse events leading to morbidity will be measured. However, since the observed time period may not allow us to observe any significant impact on mortality, the Kt/V_{urea} measure will be used as a surrogate marker for survival, and quality adjusted life years will be estimated on this basis using USRDS data. Given the high correlation between Kt/V_{urea} and serum albumin, only Kt/V_{urea} will be measured.

Preference Based Outcomes:

Quality of Life Measurements

In broad terms, quality of life can be measured using two different measurement constructs: health status and patient preference. Health status instruments or functional instruments compare patients' levels of functioning to standardized levels , the results of which are then quantified into a quality-of-life score. These global assessment measures such as (SF 36, Medical Outcome Study Short Form)[27] and the SIP may be generalized across populations of patients with different clinical conditions. However, global measures may not be sensitive to small changes in health status within therapeutic categories. This why it is important to test the different instruments to determine which one would be most appropriate to our application. Once the instrument is decided upon in Phase I, patient's health status will be observed every three months with the patient completing a survey.

In contrast to health status instruments which evaluate patient health status against standardized levels of functioning, patient preference assessments measure patients' interpretation of their health status. The patients are asked to complete two utility assessment interviews on the telemedicine system, the EuroQol and the Standard Gamble to develop utilities. Dr. Schulman has recently completed a study using the EuroQol system as well as Standard Gamble methodologies.[28] The EuroQol enables patients to evaluate their current health state using a 0 to 100 scale, whereby 0 is the worst health state and 100 is the best. Standard reference gambles offer the patient the choice between a health state of defined impairment or an option requiring patients to take a risks on their health outcomes, offering a probability of perfect health and the reciprocal probability of death. These and other preference solicitation techniques will be used if feasible, although many investigators have found these techniques to be difficult to apply.

Patient Satisfaction

Patient satisfaction will also be measured as an outcome parameter. The Patient Satisfaction Questionnaire III (PSQ-III), in its short form PSQ-18[29] , will be used. This is an instrument developed by the Rand Corporation to study seven dimensions of satisfaction

with medical care: general satisfaction, technical quality, interpersonal manner, communication, financial aspects, time spent with the physician, and accessibility and convenience. PSQ-18 subscores possess adequate internal consistency reliability.

4.1.3 Cost Data Collection

Costs that will be collected include the following:

1) Hospitalization costs: These will be based upon Medicare's diagnosis-related group system, which specifies a cost per admission according to the DRG. We will also adjust the hospitalization cost if the average length of stay is substantially different from the average length of stay for patients in that DRG category.

2) Inpatient physician billing: This information can be obtained by enumerating the services provided to each patient, which will be available through the billing systems used by physicians (which will be available to us through the Georgetown University Faculty Practice Plan billings). These billings will be coded according to their CPT-4 code and the cost will be estimated at the level of Medicare's payment for that Resource Based Relative Value Scale code. A cost of physician services to Medicare can thus be enumerated.

3) Medication costs: A tally will be kept of medications that patients are using, and standard wholesale costs will be used to estimate the costs of those medications.

4) Outpatient physician costs: Outpatient physician services will be enumerated on a weekly basis to determine visits that the patient has to physicians outside of the dialysis program. These costs will be priced in a fashion similar to those of inpatient services.

5) Diagnostic tests and procedures: A logbook will be kept to enumerate major diagnostic procedures which patients undergo, including scans, angiograms, etc.

Other costs may be included at a later date, but the aforementioned costs are those generally included in a large number of cost effectiveness and other clinical economic studies previously carried out by Drs. Eisenberg and Schulman.

In Phase I of this project, the investigators will determine the most useful information to be collected, particularly that which experts believe is most likely to be affected by the telemedicine intervention. For those elements of cost, more detailed information may be collected if feasible. Parameters that will be collected in order to help determine the costs to Medicare of the ESRD program for these patients on hemodialysis include length of time on dialysis, nephrologist's time, and Medicare rates for hemodialysis for these patients.

4.2 Data Analysis

The data described above will be collected on cost, quality of life, and satisfaction for patients, caregivers, and the health care system (including payers). Statistical methods to be used to assess this data include descriptive statistics comparing site data and sample data across types of site (telemedicine vs. control); graphical methods including box plots; crosstabulations and chi-square tests; t-tests, non-parameteric tests of location and analysis of variance and covariance. Both univariate and multivariate methods will be used. Univariate methods will take the form of standard tables of cost effectiveness, as well as incremental analysis of the alternative approaches to the care of patients with hemodialysis using telemedicine. Multivariate models will be used in order to determine the impact of telemedicine as one variable influencing a multivariate cost function.

In order to analyze data on cost, differences in the quantity of resources consumed across the groups will be analyzed and translated into cost of care using proxies for price and actual cost. Multiple linear and logistic regression techniques will be used to examine these derivations of differences in cost and the effect of telemedicine on them. Product limit methods may also be used to analyze the cost data.

For quality of life end points, survival and mortality will be analyzed, and then weighted by metrics of the utility (quality of life, patient satisfaction) information. Thus, quality adjusted life years can be derived. This may be carried out using regression techniques if appropriate. Specifically, mortality will be predicted using the regression techniques and, for those patients who are alive during this time, their utility value will be used to adjust the quality of life score so that the regression model can estimate not only survival; but also quality of life for individual patients, as measured by the integrated area under their 'quality of life curve.' This information can be aggregated across patients from both arms of the study, telemedicine and control. If no difference exists in survival within the observed time period, then the Kt/V_{urea} measure will be used as a surrogate marker for survival, and quality adjusted life years will be estimated on this basis using USRDS data.

For patient satisfaction, separate analyses will be carried out to determine whether differences exist. Baseline assessment of patient satisfaction will first be determined in Phase I.

4.3 Preliminary Results of Kt/V_{urea} and Power Analysis

Research hypotheses to be tested center around the difference between telemedicine and control sites with regard to the principal outcome measures. Sample size estimates were obtained by means of statistical power calculations, assuming repeated measures Analysis of Variance (ANOVA), and a significance (a) level = 0.05. Previous data suggest a mean Kt/V_{urea} = 1.34 (sd = 0.12). An increase in this value by 0.16 would be clinically significant, so that we anticipate detecting an effect size of 1.33 sd. Under this scenario, statistical power (1 - ß) > 0.90 would be obtained with a sample of 50 patients in each group, providing a high order of probability of finding significant differences when they in fact exist. Assuming repeated measures ANOVA and a significance level of 0.05, a reduction of 2.0 in mean hospital days between the control and telemedicine groups could be detected with a similar order of probability.

Previous data on hospitalization of dialysis patients suggest a mean of 15.8 days in hospital per patient year. From the perspective of cost, a reduction of 2.0 days for the telemedicine group would be significant. Assuming repeated measures ANOVA and a significance level of 0.05, the probability of finding a true effect of this size using a sample of 50 persons per group (i.e., statistical power) would be more than adequate.

APPENDIX I

PRELIMINARY DATA COLLECTION PROTOCOLS

Storage and Operational Requirements For Telemedicine Data Capture

Data to be captured:

Patient is evaluated through video, remote auscultation and data transmission. The database will be located at the patient site and it will be accessible from the physician's remote site.

Diagnostic Audio Requirements (Cardiac/Pulmonary Status)

Once a week for routine cases, a portion of the auscultatory findings for cardiac and pulmonary assessment is recorded and stored in the patient folder. Through the electronic stethoscope, the signal is sampled at 44-48 KHz and 16 bits of dynamic range. The transmission rate required to transmit such a signal is around 128 Kbps.

Frequency: once/week/patient (routine cases)

Source: electronic stethoscope

Sampling rate: 16 bit, 44-48 KHz

Transmission Rate: 128 Kbps

Cardiac Assessment: Areas of interest will be identified by live audio; data capture will follow.

Location: Heart, all valvular areas

Length: 15 seconds

Pulmonary: Areas of interest will be identified by live audio, data capture will follow.

Location: Lungs (right and left)

Length: 10 seconds (total 20 seconds)

Estimated storage requirements: 128 Kbps x 35 sec / 8 = .56 MByte/patient/week

Still Video Requirements: (Evaluation of Fistula)

Location: The fistula will be auscultated at arterio, venous and mid-point.

Still video capture will be used for fistula evaluation. The audio file will be captured. This will also be done with vascular ultrasound in a separate unit. The files will be downloaded and stored. The shunt still video will be captured once a week per patient and will be stored on the patient side.

Frequency: once/week/patient

Resolution: 640 x 480 x 24 bit color

Source: Video camera

Estimated Storage Requirements: .92 Mbyte/patient/week

Motion Video: (Evaluation of Fistula)

Motion video will be used for video conferencing purposes including patient to physician interaction and dialogue. Mostly it will be used as a diagnostic tool for the evaluation of the fistula but also for edema, skin diseases, etc.. If images are frame grabbed, then it the requirements will be the same as for still video.

Dialysis Data Capture

Computerized dialysis machines are capable of downloading data to a central computer in order to observe changes in blood pressure, temperature, ultrafiltration rates, conductivity, transmembrane pressure, blood and dialysate flow rates, sodium delivery, etc. Data can be stored and acted upon if machine alarms are triggered and adjustable by the physician prescribing the dialysis procedure. Other data is usually needed to assess patient history such as laboratory values and patients charts.

a) From Central Server Screen:

Data will be captured from the central server through an interface with the telemedicine workstation. Data capture from the central server screen needs to be done three times during each patient session at each of the three times that the patient is scheduled for dialysis. The data capture is done once five minutes into the dialysis, at the midpoint and then again once five minutes before the end. The Fresenius machine is also capable of constructing a parameter flow diagram for each patient, each session from beginning to end. This can be stored as a JPEG file.

Frequency: 3 times/patient/session/@3 sessions/week = 9 times/patient/week
Type: Patient information: blood pressure, transmembrane pressure, ultrafiltration rate, etc.
Source: Video camera
Resolution: 320 x 240 x 8 bits
Estimated Storage Requirement: .7 Mbyte/patient/week

b) From patient charts:

Information from patient charts will be captured through a document camera. This will be freeze framed and sent as compressed JPEG file.
Source: Document camera
Type:EKG, lab values
Resolution: 320 x 240 x 8 bit
Frequency: once / month
Estimated storage requirements: .384 MByte/patient/month

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Akamai Annual Report

Chapter 7

Training and Dissemination of Information

7.1 A Training Program for Computed Radiography

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ABSTRACT

Computed Radiography (CR) is a new complex technology that is used to replace film in the radiology department. Because it is a new technology, it is important that radiologists understand the technological basis of digital imaging, the principles of image processing, and the clinical implication of digital imaging on the specific imaging task. In order to achieve the best image quality, we need to understand how different components of the system work, from imaging plate, photo-multiplier tube (PMT), laser beam for image read-out, to image processing algorithm and laser imager for hard copies. There is limited training provided by the vendors which is not sufficient. The two-day program that we developed with expert team provides a rich and sufficient information about this new technology and how to operate the CR system in order to achieve the highest sensitivity and specificity possible.

1.0 Introduction

A number of digital technologies are challenging the established screen-film (SF) technology such that the separation of image acquisition and image display are no longer applicable. One of these technologies is based on photostimulable phosphor (PSP) imaging medium used in CR.[1] The traditional SF radiography, systems' components such as image acquisition, image display, and image archiving are combined in the film medium. But in the CR system they are separate optimizable components. The CR system uses the standard radiographic machine, grids for scatter rejection, Bucky devices, and cassette similar to screen-film. Positioning of the patient is the same for as SF system. The exposure technique(s) (kVp and mAs) are also similar to SF system.

PSP digital radiography systems were introduced in the mid 80s to replace SF imaging systems.[1-3] The imaging plate for the PSP system is a new film-like image receptor[4-5] where specifically designed phosphors trap and store the radiation energy. The stored energy is stable until scanned with a laser beam, which releases the energy as luminescence. The laser beam scans the imaging plate and converts the analog signal to a digital signal that can be stored in the computer for further image processing. The basic concept of the CR system was to improve the image quality to at least equal to that of film.[6-7] The system provides good diagnostic information that produces consistently sharp images with a wide latitude. Because of the image digital format, it can be further modified through image processing, then stored for retrieval and communication in a picture archiving and communication system (PACS). In two-day training course that we designed, we give several lectures about the technical and clinical aspects of this new technology that is becoming popular in radiology department.

2.0 CR Training

The training course is designed to educate the medical physicist, radiologist, and radiologic technologist about the CR system. The Division of Imaging Science and Information Systems (ISIS Center) of Georgetown University, Department of Radiology, in cooperation with Fuji

Medical Systems, has designed this two-day training program which provides a complete overview of this new technology. The course is offered 6 times a year and is limited to maximum of 12 participants. The course provides technical aspects of computed radiography as well as the clinical aspects pertaining to many clinical applications. It also provides laboratory workshops and film interpretation sessions.

Day one of this course is devoted to the technical aspects of CR, the comparison between screen-film (SF) and CR technologies, the image quality of CR system, and image processing methodology of CR technology. The clinical aspects of CR with many clinical examples are discussed. An introduction to laboratory workshops with "hands on" experience is given. Many clinical cases are reviewed on hard copies and soft copies.

In day two, a lecture is given on the quality control of the CR system. In addition, an overview of image processing optimization is presented with many clinical cases. Then a guest speaker who is expert in his field using CR images for interpretation relates his experience of working with CR system. At the end of day two, the participants visit GUMC to observe the clinical experience of CR technology in both the inpatient and outpatient departments.

3.0 CME Credit

Georgetown University Medical Center (GUMC) is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians. The GUMC Office of Continuing Education designates this continuing medical education activity for 12 credit hours in Category 1 of the Physician's Recognition Award of the American Medical Association.

4.0 Training Facility

A dedicated facility for this course has been established in cooperation with Fuji Medical Systems at the ISIS Center. The dedicated x-ray room is equipped with general radiographic x-ray equipment and CGR Senographe 500 ts mammography machine. The next room is equipped with an AC-1$^+$ image reader and image processor with a HI-C 654 workstation for further image processing and soft copy display. Several anthropomorphic phantoms (e.g., skull, chest, pelvis, hand, foot, and physics phantoms) are available for the hands-on laboratory experiments. The reading room is equipped with RADX automatic light viewing and teaching cases that cover a variety of exams in radiography. This room is dedicated for film interpretation. In addition, the Department of Radiology is equipped with two Fuji CR model 9000s, a Fuji AC-3, two laser imagers, and two HI-C 654 workstations.

5.0 Faculty

Seong K. Mun, PhD
Associate Professor of Radiology
Director of the ISIS Center

Matthew T. Freedman, MD, MBA
Associate Professor of Radiology
Clinical Director of the ISIS Center

Wendelin S. Hayes, DO
Associate Professor of Radiology

Hamid Jafroudi, PhD
Assistant Professor of Radiology

Dorothy Artz, RT (RM)
Research Associate

Guest Speaker
Expert faculty who has clinical experience with Fuji systems

6.0 References

1. Y. Tateno, T. Iinuma, and M. Takano, Computed Radiography, Springer-Verlag, Berlin, Germany, 1987.

2. J.D. Newell, Jr. and C.A. Kelsey, Digital Imaging in Diagnostic Radiology, Churchill Livingstone, Publisher, 1990.

3. R.E. Greene and J.W. Oestmann, Computed Radiography in Clinical Practice, Thieme Medical Publishers, New York, 1992.

4. J. Miyahara, K. Takahashi, Y. Amemiya, N. Kamiya, and Y. Satow, "A new type of x-ray detector utilizing laser stimulated luminescence", Nucl. Instruments Methods Phys. Res., A246, pp. 572-578, 1986.

5. W. Hillen, U. Schiebel, and T. Zaengel, "Imaging performance of a digital storage phosphor system", Med. Phys. vol. 14(5), pp. 744-751, 1987.

6. G.D. Pond, G.W. Seeley, M.T. Yoshino, et. al., "Comparison of conventional film/screen to photostimulable imaging plate radiographs for intraoperative arteriography and cholangiography", Proc. SPIE, vol. 914, p. 138, 1988.

7. A.J. Mefibow, E.R. Beranbaum, E.J. Balthazar, et al., "Computed radiography versus film-screen radiography in double-contrast gastrointestinal radiography", Radiology, vol. 169, p. 349, 1988.

7.2 National Forum on Telemedicine

Primary Georgetown Investigator

Seong K. Mun, PhD

ABSTRACT

In order to disseminate results of telemedicine research efforts throughout the DOD environment, a telemedicine conference was organized in collaboration with the US Army and the Association of US Army. The conference program is attached as a report.

National Forum:
Global Telemedicine and Its International Implications

April 2-4, 1996
Sheraton Premiere Hotel, Tysons Corner, VA

Organized by:
The U.S. Army Medical Research and Materiel Command
in cooperation with the Association of the United States Army and
Georgetown University Medical Center

Preface

The American military health care system extends from the foxholes, ships, and air bases to the military medical centers throughout the United States and abroad. Minimizing the number of American battlefield deaths and providing medical care to all deployed men and women and their dependents around the world are fundamental missions of the DOD medical service. Advanced technologies in imaging, communication, and information systems make it possible to dramatically improve the military's ability to project effective medical care in deployment and peace time settings around the globe.

The National Forum: Telemedicine On-line Today held in March 1995 highlighted many innovative applications of telepresence technologies and established a vision of military leadership. It was a highly successful gathering of over 1,000 people representing the military, government, congress, academia, industry and foreign dignitaries.

The National Forum II: Global Telemedicine and Its International Implications will take place in the Washington, D.C. area, April 2-4, 1996 to report the progress of telemedicine initiatives, review new ideas and technologies and to plan for the future. This National Forum will focus on the global implication of telepresence and the international collaboration with a number of countries. Many military medical leaders from around the world will be invited to the Forum. The Forum will have Plenary Sessions, Workshops, Demonstration of New Capabilities and Commercial Exhibits.

The Association of the United States Army and Georgetown University Medical Center will again organize the National Forum. All interested parties are welcome to participate. We expect it to be another successful conference.

BG Russ Zajtchuk, MC, USA
Conference President
Commander, U.S. Army Medical Research and Materiel Command and
Chief Operating Officer of DoD Telemedicine Testbed

April 2, 1996

0800 **GENERAL MAXWELL THURMAN TRIBUTE**

MG Jack N. Merritt, USA (Ret.)
President, The Association of the United States Army, Arlington, VA

BG Russ Zajtchuk, MC, USA
Conference President, Commander, U.S. Army Medical Research and Materiel Command and Chief Operating Officer, DoD Telemedicine Testbed
Fort Detrick, MD

0830 **OPENING SESSION**

Chair BG Russ Zajtchuk, MC, USA
Conference President, Commander, U.S. Army Medical Research and Materiel Command and Chief Operating Officer, DoD Telemedicine Testbed
Fort Detrick, MD

Stephen C. Joseph, M.D., M.P.H.
Assistant Secretary of Defense, (Health Affairs), Washington, DC

LTG Alcide M. LaNoue, MC, USA
The Surgeon General, Department of the Army, Falls Church, VA

GEN Gordon Sullivan (Ret.)
The Association of the United States Army, Arlington, VA

GEN Yuri Chevchenko, M.D., Ph.D.
Chief of Russian Military Medical Academy, St. Petersburg, Russia

1000 **BREAK**

1030 **DEPARTMENT OF DEFENSE TELEMEDICINE POLICY PANEL DISCUSSION**

Chair COL Joan Zajtchuk, M.D.
Office of the Surgeon General, Falls Church, VA

William J. Andahazy
Professional Staff Member, House National Security Committee
Washington, DC

Nancy Alfred Persily, M.P.H., Director of Strategic Planning, Marketing and Managed Care, George Washington University
Assistant Professor of Health, George Washington School of Medicine
Washington, DC

Brigadier General Stephen N. Xenakis, Commander
Eisenhower Army Med. Ctr./South Eastern Health Service Support Activity
Fort Gordon, GA

Seth Bonder, Ph.D., President and CEO
Vector Research, Inc., Ann Arbor, MI

Tim Henderson, MSPH, Director of Primary Care Resource Center
Intergovernmental Health Policy Project
George Washington University, Washington, DC

Mark J. Schewene
Director, Advanced Government Communications Programs
Hughes Space and Communications Company

1200 **LUNCH**

1330 **BREAST CANCER DETECTION AND WOMEN'S HEALTH INITIATIVES**

Session Overview

Chair Susan J. Blumenthal, M.D., M.P.H.
Deputy Assistant Secretary for Health (Women's Health)
Assistant Surgeon General
Department of Health and Human Services, Washington, DC

1. Transfer of Intelligence Technologies to Improve Breast Cancer

Susan J. Blumenthal, M.D., M.P.H.
Deputy Assistant Secretary for Health (Women's Health)
Assistant Surgeon General
Department of Health and Human Services, Washington, DC

Sam Grant, Project Officer
Central Intelligence Agency, McLean, VA

Daniel Kopans, M.D., Director of Breast Imaging
Massachusetts General Hospital, Boston, MA

Mark Lister, Director of Operations
National Information Display Laboratory, Princeton, NJ

Mitchell Schnall, Ph.D., Associate Professor of Radiology, Director of MRI Program, University of Pennsylvania Medical Center, Philadelphia, PA

2. Transfer of Space Technologies to Improve Women's Health

Joan Vernikos, Ph.D., Director, Division of Life Sciences
NASA, Washington, DC

Faina Shtern, M.D., Chief, Diagnostic Imaging Research Branch
National Cancer Institute, DHHS, Bethesda, MD

3. Telemedicine for Educational and Research Applications in Women's Health

Norman Winarsky, Ph.D., Vice President, Information Systems
David Sarnoff Research Laboratories, Princeton, NJ

COL John Silva, M.D., Program Manager, Defense Sciences Office
Advanced Research Project Agency, DoD, Arlington, VA

1500 **BREAK**

1530 **BOSNIA UPDATE**

1800 **RECEPTION**

April 3, 1996

0830 **INTERNATIONAL SESSION**

Chair GEN Gordon Sullivan (USA Ret.)
Distinguished Senior Fellow, The Association of the United States Army
Arlington, VA

Nagaaki Ohyama, Ph.D.
Tokyo Institute of Technology, Imaging Science and Engineering Laboratory, Tokyo, Japan

David Ticoll, President
Alliance for Converging Technologies, Toronto, Ontario, Canada

Luc Bessette, M.D.
Chair, Medicine 2001 Conference, Montreal Canada

Youngsoo Shin, M.D.
Director, Korea Institute of Health Service Management, Seoul, Korea

1000 **BREAK**

1030 **ADVANCED TECHNOLOGIES AND COMBAT CASUALTY CARE**

Chair MG George Anderson, MC, USAF
Deputy Assistant Secretary of Defense
(Health Services, Operations and Readiness), Washington DC

ARPA Advanced BioMedical Technologies: Technology Transitions and New Initiatives
COL Richard Satava, MC, USA
Advanced Research Projects Agency, Arlington, VA

Donald P. Jenkins, Ph.D.
Advanced Research Projects Agency, Arlington, VA

COL John Silva, M.D.
Advanced Research Projects Agency, Arlington, VA

Paul Fontelo, M.D.
Armed Forces Institute of Pathology, Washington, DC

1200 **LUNCH**

1330 **TELEPRESENCE**

Chair CAPT Paul Tibbits, MC, USN
Commanding Officer, Naval Medical Information Management Center
Bethesda, MD

Navy Telemedicine Initiatives in the U.S.
CDR Michael Greenauer, MSC, USN, Senior Navy Liaison Officer
USAMRMC, MATMO, MCMR-AT, Fort Detrick, MD

Navy Telemedicine Initiatives in Support of the Fleet
LCDR Laura Tillery, MSC, USN
Navy Telemedicine Initiatives in Support of the Fleet, Bethesda, MD

Private-Sector-DoD Collaboration for T-Med
Dr. Gary Vanderpool, Assistant Vice Chancellor, School of Medicine
E. Carolina University

T-Med Initiatives in the Private Sector
Dr. Max Stachura, Prof. of Medicine
Medical College of Georgia

1500 **BREAK**

1530 **MDIS AND DIAGNOSTIC IMAGING PROJECTS**

Chair COL Anna Chacko, M.D., Chairman, Department of Radiology
Brooke Army Medical Center, Fort Sam Houston, TX

LTC Michael Cawthon, MC, USA, Asst. Chairman, Department of Radiology
Brooke Army Medical Center, Fort Sam Houston, TX

LTC Jay Cook, MC, Department of Radiology
Tripler Army Medical Center, Honolulu, HI

Duk-Woo Ro, Ph.D.
Samsung Medical Center, Seoul, Korea

The Use of Multiadaptive Telemedicine Workstation in Various Networking Environments
William J. Chimiak, Ph.D., Assistant Professor
Department of Radiology, Wake Forest University, Winston-Salem, NC

April 4, 1996

0830 **TELEMEDICINE ACTIVITIES OF VETERANS ADMINISTRATION, DOD AND OTHER FEDERAL AGENCIES**

Chair Eliot Siegel, M.D.
Veterans Administration Hospital, Baltimore, MD

Roger Shannon, M.D.
Program Coordinator for Radiology, Veterans Administration Washington, DC

Robert Kolodner, M.D.
Acting Chief Information Officer

Ruth E. Dayhoff, M.D.
DHCP Imaging Project, Department of Veteran Affairs
Washington Information Systems Center, Silver Spring, MD

Peter Kuzmak
Department of Veterans Affairs, Silver Spring, MD

1000 **BREAK**

1030 **NATIONAL INFORMATION INFRASTRUCTURE AND TELEMEDICINE**

Chair Michael J. Ackerman, Ph.D.
Asst. Dir. for High Performance Computing and Communications
National Library of Medicine, Bethesda, MD

Dena Puskin, Ph.D., Deputy Director
Office of Rural Health Policy, Rockville, MD

William England, Ph.D., J.D., Project Officer
Telecommunications Demonstrations, ORD/HCFA, Baltimore, MD

Steve Downs, Telecommunications Policy Analyst
US Department of Commerce, National Telecommunications and
Information Administration, Washington, DC

Steve Downs
Telecommunications Policy Analyst, US Department of Commerce
National Telcommunications and Information Administration
Washington, DC

Larry Bryant, Branch Chief
Telemedicine & Distance Learning, Rural Utilities Services, Washington, DC

Michael J. Ackerman, Ph.D., Asst. Dir. for High Performance Computing
and Communications, National Library of Medicine Bethesda, MD

1200 **LUNCH**

1330 **TELEMEDICINE EVALUATION**

Chair MG Charles Roadman, MC, USAF
Deputy Surgeon General, U.S. Air Force, Washington, DC

COL Harrison Hassell, MC, USA
Chief of Clinical Investigation, MCHK-CI, Tripler Army Medical Center, HI

Tim Reardon
Vector Research, Inc., Ann Arbor, MI

MAJ Scott Norton
Department of Dermatology, Tripler Army Medical Center, HI

LTC Roy Philips
Chief of Evaluation, AMED Board, Fort Sam Houston, TX

Linda Brink, Ph.D.
Walter Reed Army Medical Center, T-Med/MDIS Project, Washington, DC

1500 **BREAK**

1530 **INTERNATIONAL SESSION**

Chair Betsy Blakeslee, Ph.D.
Center for Total Access, Eisenhower Army Medical Center, Fort Gordon, GA

Hendry Andersson
Head of Division Stockholm County Council, Stockholm, Sweden

John C. Scott
President, Center for Public Service Communications, Arlington, VA

Silas Olsson, M.Sc.
Swedish Planning and Rationalization Institute of the Health and Social Services, Department of Health Economics, Stockholm, Sweden

Dr. Yoon-Ping Chui
Research Fellow, Human Factors Division
Defense Medical Research Institute
Republic of Singapore